

EPA REGISTRATION NUMBER 432-1541



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 19, 2019

Terrie Moore
Regulatory Affairs Manager
Bayer CropScience
Environmental Science division
2 T.W. Alexander Drive
RTP, NC 27709

Subject: Registration Review Label Mitigation for Fosetyl-Al
Product Name: 12ESP705 Fungicide
EPA Registration Number: 432-1541
Application Date: October 7, 2016
Decision Number: 553781

Dear Terrie Moore:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Fosetyl-Al Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions about this letter, please contact Darius Stanton by phone at 703-347-0433, or via email at Stanton.Darius@epa.gov.

Page 2 of 2
EPA Reg. No. 432-1541
Decision No. 553781

Sincerely,



Linda Arrington, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-Evaluation Division
Office of Pesticide Programs

Enclosure

ALUMINUM TRIS	GROUP	P07	FUNGICIDE
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12ESP705 FUNGICIDE

ABNS: Signature Xtra Stressgard , Chipco Signature Xtra Stressgard, Signature Xtra

A plant health promoting systemic fungicide.

ACTIVE INGREDIENT:

Aluminum tris (O-ethyl phosphonate).....60.00%

OTHER INGREDIENTS.....40.00%

TOTAL:.....100.0%

EPA Reg. No. 432-1541

EPA Est. No.

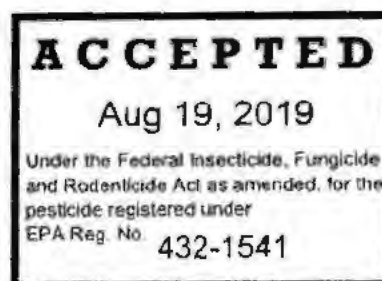
KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back][Side] Panel for First Aid Instructions and [Leaflet][Booklet] for Complete Precautionary Statements and Directions for Use. (Note to reviewer: Location of additional precautionary statements, directions for use will vary between those listed, depending on container type/size.)

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-800-331-2867

Net Contents:



PRODUCED FOR



Bayer Environmental Science
A Division of Bayer CropScience, LP
5000 CentreGreen Way, Suite 400
Cary, NC 27513

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything to an unconscious person.
If in eyes:	<ul style="list-style-type: none"> • Hold eyes open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of medical emergency for additional information call toll free 1-800-334-7577	
NOTE TO PHYSICIAN: Treat symptomatically	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

- Harmful if swallowed.
- Causes moderate eye irritation.
- Avoid contact with eyes or clothing.
- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE):

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks
- Chemical resistant gloves made of any waterproof material.

Engineering Controls:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
Users should: <ul style="list-style-type: none"> • Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. • Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. • Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters.

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 48 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- coveralls over long-sleeved shirt and long pants,
- socks and shoes,
- chemical-resistant gloves made of any of any waterproof material such as natural rubber \geq 14 mils.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter allow others to enter the treated area until sprays have dried.

PRODUCT INFORMATION

12ESP705 FUNGICIDE is a plant health promoting systemic fungicide.

For use on:

- Turf on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites.

PLANT HEALTH

12ESP705 FUNGICIDE when applied at the prescribed rates and intervals promotes healthier roots, increases plant drought tolerance, and improves plant water utilization. This leads to a reduction in the need for hand watering and a general saving of water use. The resulting improvement in function of these healthier roots leads to more efficient uptake of plant nutrients improving cell turgidity and results in a healthier and sturdier plant structure reducing the impact of traffic or mechanical damage. These effects are consistent with the properties of anti-oxidants. A property of **12ESP705 FUNGICIDE** is to act as an inducer of systemic resistance in plants resulting in production of plant metabolites responsible for maintaining plant processes.

Cool season grasses such as tall fescues, bluegrasses and bentgrasses are prone to damage during summer heat and summer decline leading to reduced root mass in the summer months. Turf treated with **12ESP705 FUNGICIDE** retains turf quality through summer stress by alleviating plant stresses, enhancing disease resistance through induced system resistance and protecting the plant from the adverse effects of solar radiation.

Warm season grasses such as bermudagrass and zoysiagrass, influenced by the effects of insufficient sunlight, are prone to losing chlorophyll and premature senescence. **12ESP705 FUNGICIDE** reduces the negative effects of low light conditions, supports earlier spring green up, turf fill in and extends turf quality.

12ESP705 FUNGICIDE when applied in a program with turf growth regulators further enhances the overall quality of the turf.

APPLICATION INFORMATION

12ESP705 FUNGICIDE must be applied as a foliar spray using ground application equipment. Apply in 1 to 5 gallons of spray solution per 1000 sq ft.

This product may cause staining. Avoid off-target sites such as sidewalks, patios, driveways, pavers, or similar materials. Do not enter treated areas until spray has dried. Rinse spray equipment thoroughly with warm water and detergent.

SPRAY MIXING AND COMPATIBILITY

12ESP705 FUNGICIDE may not be chemically compatible with foliar fertilizers or with copper-based fungicides and phytotoxicity may occur. To determine the physical compatibility of **12ESP705 FUNGICIDE** with any other product, use a small container to mix a small amount (e.g. 1 pint) of spray solution, containing all ingredients in the same order and ratio as the anticipated use. If any indication of physical incompatibility develops, do not use this mixture for spraying. Indication of incompatibility usually appears within 5 - 15 minutes after mixing. Read and follow all directions and precautions on this label and on the labels of any products for which a tank mixture is being considered.

PRODUCT USE RESTRICTIONS

- Do not exceed a total of 240 lbs of product per acre (144 lb a.i./A), per year.
- Do not graze animals on treated turf.
- Do not feed clippings from treated turf to livestock and poultry.
- Apply by ground application equipment only. Do not apply by air unless directed by Supplemental or Special Local Need labeling.

TURF USE DIRECTIONS

12ESP705 FUNGICIDE is a systemic fungicide, which may be used, in a seasonal program for the control of Pythium diseases, such as blight and root rot, and yellow tuft on common turfgrasses on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites. Apply as a foliar spray, using 1 to 5 gallons of spray solution per 1,000 square feet, as indicated in the table below. Apply with a properly calibrated sprayer. Maintain agitation during spray operations.

When applying use spray nozzles that will deliver fine or larger spray droplets as defined in the American Society of Agricultural and Biological Engineers (ASABE) standard ANSI/ASAE S572.1 (March 2009).

PLANT HEALTH

12ESP705 FUNGICIDE has a plant health component that is used for the prevention or alleviation of stress from solar radiation and other oxidative processes on turfgrasses. Begin preventative applications prior to the occurrence of adverse weather conditions and repeat at prescribed intervals. Use higher rates prior to the onset of severe stress. **12ESP705 FUNGICIDE** does not replace the use of soil amending adjuvants for soil hydrophobicity and must be used in conjunction with best turf management practices.

STRESS MANAGEMENT	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
<p>Stresses such as</p> <ul style="list-style-type: none">• high solar radiation[**]• high wilt potential[**]• winter cold injury* [**]• hot and humid weather[**]• traffic wear[**]• physical or mechanical damage[**]• injury from the use of turf growth regulators[**]• injury from disease[**]• reduced mowing heights[**]	2 - 4	7 - 14	<p>Extend application interval beyond 14 days when climatic conditions are less favorable for turf growth. Do not mow or irrigate treated area until sprays have completely dried.</p>
	4 - 6	14 - 21	
<p>*Apply after damage has occurred [** Stress management not applicable for use in California] Do not exceed a total of 240 lbs of product per acre (144 lb a.i./A) per year</p>			

APPLICATIONS FOR TURF DISEASES

APPLICATIONS FOR TURF DISEASES			
DISEASE	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Pythium diseases, Yellow tuft	2 - 4	7-14	Begin preventive foliar spray application when conditions first favor disease and repeat at prescribed interval. Use the highest rate for the longer interval. Do not mow or irrigate treated area until sprays have completely dried.
	4 - 6	14 - 21	
Bacterial Wilt	2 - 4	7	Use the more frequent interval when severe symptoms appear.
	6	14	
Do not exceed a total of 240 lbs of product per acre (144 lb a.i./A), per year.			

USE AS A RESISTANCE MANAGEMENT TOOL

For resistance management, please note that 12ESP705 FUNGICIDE contains a Group P07 [phosphonates] fungicide. Any fungal population may contain/develop individuals naturally resistant to 12ESP705 FUNGICIDE and other Group P07 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide resistance, take one or more of the following steps:

- Use tank mixtures with fungicide from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.

- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.
- For further information or to report suspected resistance contact Bayer CropScience at 1-866-99BAYER (1-866-992-2937). You can also contact your pesticide distributor or university extension specialist to report resistance.

TANK MIXTURES

It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store in original container and keep tightly closed when not in use. Store in a cool dry place. Avoid cross-contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticides wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

CONTAINER HANDLING

Rigid Non-refillable Containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable container. Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Non-Seed Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Non-Seed Treatment Products in Non-Refillable Foil outer pouches of Water soluble Packets (WSP)

Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken.

Rigid Non-Refillable containers with capacities smaller or equal to 5 gallons

PLASTIC CONTAINERS:

Non refillable container. Do not reuse or refill this container. Tripled rinse container (or equivalent) promptly after emptying.

SOLID Dillutable formulations:

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

Non-Seed Treatment Products in Non-Rigid, Non-refillable Containers = BAGS

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Pending 10/07/2015, 09/23/2016, 09/27/2016, 02/04/2018, 02/26/2018, 12/16/2018, 12/20/2018, 01/31/2019, 02/04/2019, 07/27/2019



October 7, 2016

Mr. Ricardo Jones
U.S. Environmental Protection Agency
Pesticide Re-evaluation Division (7508P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: Label Changes for Fosetyl-Al Registration Review (EPA-HQ-OPP-2007-0379)

Dear Mr. Jones,

Environmental Science, a division of Bayer CropScience would like to submit a label change for 2 Fosetyl-Al labels: Aliette WDG (432-890) and 13ESP705 (432-1541). There are 2 other Fosetyl-Al that we would like to cancel: Chipco Aliette WSP (432-894) and Aliette HG (432-897). These 2 products will be canceled at the renewal period at the end of 2016.

The changes on the labels Aliette WDG (432-890) and 13ESP705 (432-1541) are required by the Fosetyl-Al Interim Registration Review Decision (EPA-HQ-OPP-2007-0379) and follow the format of the proposed label for Aliette WDG (432-890) that was sent to the Agency for review. The Memorandum dated February 27, 2013 (PC code 123301) is attached to this submission for your reference.

In addition to the required changes, we made several changes on the 13ESP705 (432-1541) to satisfy CDPR requests. These changes include:

- Deleted - "that alleviates stress from both abiotic and biotic sources"
- Deleted - "high will potential" and "injury from disease"
- Deleted - Entire tank mix section

We also would like to request that you to take into consideration an 18 month label transition period after this label change is approved by the Agency. The 18 month time period would allow time for state submissions and approvals which for some states can take 6-12 months or longer.

Enclosed with this submission are the following documents:

- 8570-1 form
- 2 copies of each label including shaded labels for 432-890 and 432-1541
- Memorandum dated February 27, 2013 (PC code 123301)

If you have any questions, contact me at (919) 549-5678 or email me at terrie.moore@bayer.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Terrie Moore', with a long horizontal flourish extending to the right.

Terrie Moore
Regulatory Affairs Manager



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1541	2. EPA Product Manager Ricardo Jones	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 12ESP705 Fungicide	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience, Environmental Science division 2 T.W. Alexander Drive, RTP, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add Registration Review changes

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Terrie Moore	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) 919-549-5678	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
Signature 	3. Title Regulatory Affairs Manager		
Typed Name Terrie Moore	5. Date 10/7/16		

ALUMINUM TRIS	GROUP	33 P07	FUNGICIDE
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12ESP705 FUNGICIDE

ABNS: Signature Xtra Stressgard , Chipco Signature Xtra Stressgard, Signature Xtra

A plant health promoting systemic fungicide. that alleviates stress from both abiotic and biotic sources.

ACTIVE INGREDIENT:

Aluminum tris (O-ethyl phosphonate):.....60.00%

OTHER INGREDIENTS:.....40.00%

TOTAL:.....100.0%

EPA Reg. No. 432-1541

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

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See [Back][Side] Panel for First Aid Instructions and [Leaflet][Booklet] for Complete Precautionary Statements and Directions for Use. (Note to reviewer: Location of additional precautionary statements, directions for use will vary between those listed, depending on container type/size.)

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PRODUCED FOR



Bayer Environmental Science
A Division of Bayer CropScience, LP
5000 CentreGreen Way, Suite 400
Cary, NC 27513

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- Avoid contact with eyes or clothing.
- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE):

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks
- Chemical resistant gloves made of any waterproof material.
- Chemical-resistant (such as natural rubber) gloves (if more options are needed, follow the instructions for category A on an EPA chemical-resistance category selection chart).

Engineering Controls:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

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CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of **12 48** hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- coveralls over long-sleeved shirt and long pants,
- socks and shoes,
- chemical-resistant gloves made of any of any waterproof material such as natural rubber \geq 14 mils.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter allow others to enter the treated area until sprays have dried.

PRODUCT INFORMATION

12ESP705 FUNGICIDE is a plant health promoting systemic fungicide. ~~that alleviates stress from both abiotic and biotic sources.~~

For use on:

- Turf on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites.

PLANT HEALTH

12ESP705 FUNGICIDE when applied at the prescribed rates and intervals promotes healthier roots, increases plant drought tolerance, and improves plant water utilization. This leads to a reduction in the need for hand watering and a general saving of water use. The resulting improvement in function of these healthier roots leads to more efficient uptake of plant nutrients improving cell turgidity and results in a healthier and sturdier plant structure reducing the impact of traffic or mechanical damage. These effects are consistent with the properties of anti-oxidants. A property of **12ESP705 FUNGICIDE** is to act as an inducer of systemic resistance in plants resulting in production of plant metabolites responsible for maintaining plant processes.

Cool season grasses such as tall fescues, bluegrasses and bentgrasses are prone to damage during summer heat and summer decline leading to reduced root mass in the summer months. Turf treated with **12ESP705 FUNGICIDE** retains turf quality through summer stress by alleviating plant stresses, enhancing disease resistance through induced system resistance and protecting the plant from the adverse effects of solar radiation.

Warm season grasses such as bermudagrass and zoysiagrass, influenced by the effects of insufficient sunlight, are prone to losing chlorophyll and premature senescence. **12ESP705 FUNGICIDE** reduces the negative effects of low light conditions, supports earlier spring green up, turf fill in and extends turf quality.

12ESP705 FUNGICIDE when applied in a program with turf growth regulators further enhances the overall quality of the turf.

APPLICATION INFORMATION

12ESP705 FUNGICIDE must be applied as a foliar spray using ground application equipment. Apply in 1 to 5 gallons of spray solution per 1000 sq ft.

This product may cause staining. Avoid off-target sites such as sidewalks, patios, driveways, pavers, or similar materials. Do not enter treated areas until spray has dried. Rinse spray equipment thoroughly with warm water and detergent.

SPRAY MIXING AND COMPATIBILITY

12ESP705 FUNGICIDE may not be chemically compatible with foliar fertilizers or with copper-based fungicides and phytotoxicity may occur. To determine the physical compatibility of **12ESP705 FUNGICIDE** with any other product, use a small container to mix a small amount (e.g. 1 pint) of spray solution, containing all ingredients in the same order and ratio as the anticipated use. If any indication of physical incompatibility develops, do not use this mixture for spraying. Indication of incompatibility usually appears within 5 - 15 minutes after mixing. Read and follow all directions and precautions on this label and on the labels of any products for which a tank mixture is being considered.

PRODUCT USE RESTRICTIONS

- Do not exceed a total of 240 lbs of product per acre (144 lb a.i./A), per year.
- Do not graze animals on treated turf.
- Do not feed clippings from treated turf to livestock and poultry.
- Apply by ground application equipment only. Do not apply by air unless directed by Supplemental or Special Local Need labeling.

TURF USE DIRECTIONS

12ESP705 FUNGICIDE is a systemic fungicide, which may be used, in a seasonal program for the control of Pythium diseases, such as blight and root rot, and yellow tuft on common turfgrasses on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites. Apply as a foliar spray, using 1 to 5 gallons of spray solution per 1,000 square feet, as indicated in the table below. Apply with a properly calibrated sprayer. Maintain agitation during spray operations.

When applying use spray nozzles that will deliver fine or larger spray droplets as defined in the American Society of Agricultural and Biological Engineers (ASABE) standard ANSI/ASAE S572.1 (March 2009).

PLANT HEALTH

12ESP705 FUNGICIDE has a plant health component that is used for the prevention or alleviation of stress from solar radiation and other oxidative processes on turfgrasses. Begin preventative applications prior to the occurrence of adverse weather conditions and repeat at prescribed intervals. Use higher rates prior to the onset of severe stress. **12ESP705 FUNGICIDE** does not replace the use of soil amending adjuvants for soil hydrophobicity and must be used in conjunction with best turf management practices.

STRESS MANAGEMENT	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
<p>Stresses such as</p> <ul style="list-style-type: none">• high solar radiation[**]• high wilt potential[**]• winter cold injury* [**]• hot and humid weather[**]• traffic wear[**]• physical or mechanical damage[**]• injury from the use of turf growth regulators*[**]• injury from disease[**]• reduced mowing heights[**]	2 - 4	7 - 14	<p>Extend application interval beyond 14 days when climatic conditions are less favorable for turf growth. Do not mow or irrigate treated area until sprays have completely dried.</p>
	4 - 6	14 - 21	
<p>*Apply after damage has occurred</p> <p>[** Stress management not applicable for use in California]</p> <p>Do not exceed a total of 240 lbs of product per acre (144 lb a.i./A), per year.</p>			

APPLICATIONS FOR TURF DISEASES

APPLICATIONS FOR FERT DISEASES			
DISEASE	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Pythium diseases, Yellow tuft	2 - 4	7-14	Begin preventive foliar spray application when conditions first favor disease and repeat at prescribed interval. Use the highest rate for the longer interval. Do not mow or irrigate treated area until sprays have completely dried.
	4 - 6	14 - 21	
Bacterial Wilt	2 - 4	7	Use the more frequent interval when severe symptoms appear.
	6	14	
Do not exceed a total of 240 lbs of product per acre (144 lb a.i./A), per year.			

USE AS A RESISTANCE MANAGEMENT TOOL

Fosetyl-Al has no history of resistance development in plant pathogenic fungi; include **12ESP705 FUNGICIDE** as a mixture or rotation partner in programs to manage resistance for fungicides with a high risk of resistance to labeled diseases.

USE AS A RESISTANCE MANAGEMENT TOOL

For resistance management, please note that **12ESP705 FUNGICIDE** contains a Group P07, [phosphonates] fungicide. Any fungal population may contain/develop individuals naturally resistant to **12ESP705 FUNGICIDE** and other Group P07 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide resistance, take one or more of the following steps:

- Use tank mixtures with fungicide from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.
- For further information or to report suspected resistance contact Bayer CropScience at 1-866-99BAYER (1-866-992-2937). You can also contact your pesticide distributor or university extension specialist to report resistance.

TANK MIXTURES

It is the pesticide user's responsibility to ensure that all products are registered for the intended use. Read and follow the applicable restrictions and limitations and directions for use on all product labels involved in tank mixing. Users must follow the most restrictive directions for use and precautionary statements of each product in the tank mixture.

TANK MIXTURES

A-12ESP705 FUNGICIDE program encourages the development of a thick, vigorous turf stand that is better able to tolerate various stresses (heat, humidity, drying winds, traffic etc) that can have a negative effect on turf health. A thick, vigorous **12ESP705 FUNGICIDE** treated turf is better able to resist disease development and suppress the development of other pests such as weeds and algae.

Summer Decline: For control of Summer Decline caused by a complex of *Pythium* and *Rhizoctonia* diseases, **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. Do not exceed label dosage rates. This product cannot be mixed with any product containing a label prohibition against such mixing.

Anthrachnose: For improved control of anthracnose **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable to anthracnose.

Bentgrass Dead Spot: For control of bentgrass dead spot, **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable for development of bentgrass dead spot.

PRODUCT	RATE FL OZ/OZ* PRODUCT/1,000 SQ FT	DISEASE	APPLICATION INTERVAL
12ESP705 FUNGICIDE + 26GT™ or Interface Stressgard or Tartan Stressgard or Mirage Stressgard or Daconil-Ultrex® or Daconil-Action® or Fore® Rainshield™	3.0 to 6.0* + 3.0 to 5.0 or 1.0 to 2.0 or 1.0 to 2.0 or 3.2* or 3.6 or 4.0 to 6.0	Summer Decline (<i>Pythium</i> and <i>Rhizoctonia</i> spp.) and/or Anthracnose (<i>Colletotrichum</i> <i>graminicola</i>)	7-14 days
12ESP705 FUNGICIDE + Interface Stressgard or Fore® Rainshield™ or Daconil-Ultrex®	3.0 to 6.0 + 3.0 to 5.0 or 6.0 or 3.2*	Leaf spots Bermudagrass Decline	7-14 days

Do not exceed a total of 240 lb of product per acre, per year.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store in original container and keep tightly closed when not in use. Store in a cool dry place. Avoid cross-contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticides wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

CONTAINER HANDLING

Rigid Non-refillable Containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable container. Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Non-Seed Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Non-Seed Treatment Products in Non-Refillable Foil outer pouches of Water soluble Packets (WSP)

Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken.

Rigid Non-Refillable containers with capacities smaller or equal to 5 gallons

PLASTIC CONTAINERS:

Non refillable container. Do not reuse or refill this container. Tripled rinse container (or equivalent) promptly after emptying.

SOLID Dillutable formulations:

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

Non-Seed Treatment Products in Non-Rigid, Non-refillable Containers = BAGS

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Pending 10/07/2015, 09/23/2016, 09/27/2016, 02/04/2018, 02/26/2018, 12/18/2018, 12/20/2018, 01/31/2019, 02/04/2019, 07/27/2019

Reg Number: 432-1541 Reg. Type: Product Registration - Section 3
Name: 12ESP705 FUNGICIDE

Status: Conditionally Registered (06-Mar-2
<View Registration Details>

(New Receipts)			
S:	Submission Type	OPP Recvd Date	Description
X 597210	Amendment	07-Nov-2016	Partial submission page 1-577 FFD action. Fast track Label changes as required by the interim registration review decision
1219512	Amendment	19-Feb-2017	Partial submission page 1-577 Label amendment

Decisions

- D: Closed 552781 432-1541 579 REGISTRATI
- Data Requirements**
 - D: Closed 507368 432-1541 360 ACTION INT
 - 75-Day Letters
 - S 1000648 3-12-2017 Amendment 432
 - S 901565 7-21-2015 Amendment 432
 - D: Closed 502672 432-1541 332 NOTIFICATION
 - D: Closed 493775 432-1541 P210 NEW ENCL

Decision Sequence: 507368

Action: 360 ACTION INITIATED BY THE AGENCY:
Number: 432-1541 Original Decision:
Name: 12ESP705 FUNGICIDE
Decision Status: COMPLETED (24-Jan-2018)
Organization Owner: RD / FHE
Team Owner: RM 20
FFS Start Date Received by Risk Manager:
Due Date 01-Jul-2017 FFS Amt Expected:
Negotiated Due Date: FFS Amt Refunded:
FFS Amt Received: \$0

Comments: Efficacy data was not reviewed. However certain label changes were made by the registrant and submitted as part of registration review. The label will be review under the 576 decision

Balan, Aswathy

From: Balan, Aswathy
Sent: Tuesday, January 23, 2018 2:51 PM
To: Kaul, Monisha
Subject: RE: Bean DP# 439815 (Fosetyl-al)

Hi Monisha. The subject bean DP# 439815 is still open. Can you close it out?

FYI, we had discussions on this bean last year but BEAD never did any review.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Kaul, Monisha
Sent: Friday, May 12, 2017 4:30 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: Joyner, Shaja <Joyner.Shaja@epa.gov>; Cook, Colwell <cook.colwell@epa.gov>
Subject: RE: Bean DP# 439815 (Fosetyl-al)

Hello Aswathy,

I'd like to talk through this request with you so we can better understand what's needed and if a BEAD review is appropriate. Let's try for some time next week.

Thank you.

Monisha

From: Balan, Aswathy
Sent: Wednesday, May 03, 2017 9:54 AM
To: Kaul, Monisha <Kaul.Monisha@epa.gov>
Cc: Joyner, Shaja <Joyner.Shaja@epa.gov>
Subject: Bean DP# 439815 (Fosetyl-al)

Hi Monisha,

Please find attached the bean for efficacy review of a fosetyl-al product 432-1541.

CDPR brought to our attention various misleading efficacy claims in the label for this fosetyl-Al product. One among them was the anti-oxidant property of this product. Upon enquiry, the registrant referenced the attached article. Relevant information has been highlighted by the registrant. According to them, this peer-reviewed journal article shows evidence that fosetyl-Al inhibits oxidation and therefore has properties that are consistent with anti-oxidants. RD would like BEAD to review the attached article to check whether this article substantiates or is supportive of this particular

claim on the label. The formal submission of this article can be found in Documentum under MRID 50267901. I have also attached a copy of the label for your reference. Please let me know if there are any questions.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP OPP RD
Environmental Protection Agency
Ph: 703-347-0510

Signature Xtra (432-1541):

- Do not exceed 6 oz SIGNATURE XTRA per 1000 sq. ft. per application; do not apply more than 14 applications per year at this rate.
- Do not apply more than 144 lb a.i. per acre, per year regardless of formulation or method of application.

Chipco Signature (432-890):

- Do not exceed 8 oz CHIPCO SIGNATURE per 1000 sq. ft. per application; do not apply more than 8 applications per year at this rate.
- Do not apply more than 144 lb a.i. per acre, per year regardless of formulation or method of application.

Aliette (432-890): *For use in Ornamentals*

- For foliar applications, do not exceed 5 lbs ALIETTE per application, per acre, per crop; do not apply more than 36 foliar applications per crop, per year at this rate.
- For drench applications, do not exceed 0.8 lbs ALIETTE per 100 gallon drench; do not apply more than 12 drench treatments per acre, per crop, per year
- Do not apply more than 144 lb a.i. per acre, per crop, per year regardless of formulation or method of application.

Phone Conference: 9/6/2017

EPA: Shaja Joyner, Rachel Holloman, Linda Arrington, Ricardo Jones

Bayer Environmental Science: Brad Glenn, Karen Shearer, Terrie Moore

Meeting Purpose: Bayer Environmental Science (BES) recommended that Fosetyl-AI product labels, 432-890 and 432-1541 specify a maximum yearly application rate (MYR) of 144 lb a.i./A/year, to be clear across all Fosetyl-labels, and consistent with current labeling practices in fungicides and consistent with risk assessment rates.

EPA: Fosetyl-AI is subject to an ESA, and application # is really needed, but they understood concern with only the inclusion of an application number limit

EPA (Ricardo): Main goal of EPA is to define clarity to the user, as well as consistency across the labels.

Action: BES to send a proposal to EPA (i.e. one pager) for a consistent and enforceable language recommendation for easy understanding of maximum yearly rate for users with every effort to reference a numerical application limit.

Process:

EPA would likely have to issue a public document to require other registrants to align & keep transparency

Perhaps this would be an amended ID, or a memo with the timeline of label submissions adjusted.

The BES proposal would be sent directly to Linda Arrington, two weeks from today (September 20th, 2017 by COB).

Balan, Aswathy

From: Holloman, Rachel
Sent: Tuesday, October 03, 2017 9:50 AM
To: Arrington, Linda
Cc: Joyner, Shaja; Balan, Aswathy
Subject: RE: Fosetyl-AI Label Mitigations

I am including Shaja and Aswathy. I believe they were more vocal on this matter.

From: Arrington, Linda
Sent: Tuesday, October 03, 2017 9:47 AM
To: Holloman, Rachel <Holloman.Rachel@epa.gov>
Subject: FW: Fosetyl-AI Label Mitigations

Did I say I was going to get back with them? I recall the answer is still the same, no more than 11 applications but they can add (max lb per year ai). Right?

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Brad Glenn [<mailto:brad.glenn@bayer.com>]
Sent: Monday, October 02, 2017 2:31 PM
To: Arrington, Linda <Arrington.Linda@epa.gov>
Cc: BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: Fosetyl-AI Label Mitigations

Hi Linda,

Good afternoon, and thank you for reviewing. I wanted to check to see if there were any points I may be able to offer clarification?

Look forward to hearing from you and the team.

Best regards,

Brad Glenn, Ph.D.
Federal Regulatory Affairs Manager
Environmental Science Business

Bayer: Science for a Better Life

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Mobile +1 919 475-7629
E-mail brad.glenn@bayer.com
Web <http://www.bayer.com>

From: Arrington, Linda [<mailto:Arrington.Linda@epa.gov>]
Sent: Friday, September 22, 2017 10:18 AM
To: Brad Glenn
Cc: BCSReg_Archive
Subject: RE: Fosetyl-AI Label Mitigations

Hi Brad,

Thanks for getting back with us. I have forward your email to the participants of the meeting and will set up a meeting next week with them to discuss. I will contact you shortly.

Thanks and have a great weekend.

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Brad Glenn [<mailto:brad.glenn@bayer.com>]
Sent: Wednesday, September 20, 2017 3:30 PM
To: Arrington, Linda <Arrington.Linda@epa.gov>
Cc: BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: Fosetyl-AI Label Mitigations

Dear Linda,

I hope this email finds you well. I wanted to follow up on our dialogue focused on consistent and enforceable label mitigations for our Fosetyl-AI turf and ornamental product labels (432-890 and 432-1541).

Attached you will find our use restriction statements. The focus was to ensure each statement was consistent with each applicable label, and provided clarity to the applicator in defining the MYR and single application rate(s). Each of these are in-line with the currently approved use patterns and labels.

Upon your review, please advise on the next steps to proceed with amending our product labels.

In addition, if there are any questions please feel free to call or email.

Thank you &
Best regards,

Brad Glenn, Ph.D.
Federal Regulatory Affairs Manager
Environmental Science Business

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Mobile: +1 919 475-7629
E-mail: brad.glenn@bayer.com
Web: <http://www.bayer.com>

From: Brad Glenn
Sent: Friday, September 08, 2017 11:49 AM
To: 'Arrington, Linda'

Cc: BCSReg_Archive
Subject: RE: Fosetyl-Al Label Mitigations

Hi Linda,

Thank you again for the phone call surrounding our Fosetyl-Al use patterns and MYR discussion. I have included the meeting minutes for your records. If there is any addition needed, please let me know. We will be in touch within two weeks for our proposal.

I hope that you have a nice weekend.

Best regards,

Brad Glenn, Ph.D.
Federal Regulatory Affairs Manager
Environmental Science Business

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Web: <http://www.bayer.com>

From: Arrington, Linda [<mailto:Arrington.Linda@epa.gov>]
Sent: Wednesday, September 06, 2017 7:53 AM
To: Brad Glenn; Terrie Moore
Cc: Karen Shearer; BCSReg_Archive; BCSReg_Archive
Subject: RE: Fosetyl-Al Label Mitigations

Thanks Brad.

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Brad Glenn [<mailto:brad.glenn@bayer.com>]
Sent: Tuesday, September 05, 2017 4:49 PM
To: Arrington, Linda <Arrington.Linda@epa.gov>; Terrie Moore <terrie.moore@bayer.com>
Cc: Karen Shearer <karen.shearer@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: Fosetyl-Al Label Mitigations

Dear Linda,

Thank you for the confirmation on the time. I have attached the updated set of slides for our review tomorrow. I apologize for the multiple copies shared. We will use this version to go over in our meeting.

Best regards,

Brad Glenn, Ph.D.
Federal Regulatory Affairs Manager
Environmental Science Business

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E-mail: brad.glen@bayer.com
Web: <http://www.bayer.com>

From: Arrington, Linda [<mailto:Arrington.Linda@epa.gov>]
Sent: Tuesday, September 05, 2017 2:31 PM
To: Brad Glenn; Terrie Moore
Cc: Karen Shearer; BCSReg_Archive; BCSReg_Archive
Subject: RE: Fosetyl-AI Label Mitigations

The time is still set for 3 pm. I will send the skype information for the meeting.

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Brad Glenn [<mailto:brad.glen@bayer.com>]
Sent: Tuesday, September 05, 2017 1:09 PM
To: Arrington, Linda <Arrington.Linda@epa.gov>; Terrie Moore <terrie.moore@bayer.com>
Cc: Karen Shearer <karen.shearer@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: Fosetyl-AI Label Mitigations

Dear Linda,

Touching base to check in on our timing for tomorrow's (9/6 @ 3pm EST) meeting on Fosetyl-AI. Attached are the set of slides that we will go through. In addition, I have included a conference line below. If you are able to open and join Skype, that would be great as we can share our slides. If not, that is okay too, we will only use the associated call in number and conference ID.

Please let me know if any questions. Thank you and look forward to talking tomorrow.

→ [Join Skype Meeting](#)

Trouble Joining? [Try Skype Web App](#)

Join by phone

[REDACTED] (USA) English (United States)
[Find a local number](#)

Conference ID: [REDACTED]
[Forgot your dial-in PIN?](#) | [Help](#)

Personal privacy information

Best regards,

Brad Glenn, Ph.D.
Federal Regulatory Affairs Manager
Environmental Science Business

Bayer: Science for a Better Life

Bayer U.S. LLC
2 T.W. Alexander Dr.
Research Triangle Park
Durham, NC 27709 United States
WW-B-1140-02

CropScience Division
Tel: +1 919 549-3958
Mobile: +1 919 475-7629
E-mail: brad.glenn@bayer.com
Web: <http://www.bayer.com>

From: Arrington, Linda [<mailto:Arrington.Linda@epa.gov>]
Sent: Tuesday, August 29, 2017 6:11 PM
To: Brad Glenn; Terrie Moore
Cc: Karen Shearer; BCSReg_Archive
Subject: RE: Fosetyl-Al Label Mitigations

Hi Brad,

Thanks for your email. I have the meeting scheduled tentatively for 9/6 from 3-4 pm. I have not heard from all the attendees so I will send out a reminder. I will let you know by Thursday if we need more dates.

Thanks

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Brad Glenn [<mailto:brad.glenn@bayer.com>]
Sent: Monday, August 28, 2017 3:24 PM
To: Arrington, Linda <Arrington.Linda@epa.gov>; Terrie Moore <terrie.moore@bayer.com>
Cc: Karen Shearer <karen.shearer@bayer.com>; BCSReg_Archive <esegamailbox@bayer.com>
Subject: RE: Fosetyl-Al Label Mitigations

Dear Linda,

I wanted to send a note to say hello, and introduce myself as the new point of contact for this product label for Fosetyl-Al. I look forward to working with you, and wanted to extend my contact information in the signature below.

Following up on setting a phone call up, I wanted to double check if any of the proposed dates would still fit within the schedule? If we need to expand the date range, please let me know.

Tues. Sept 5: 1 – 5 pm
Wed. Sept 6: 1 – 5 pm
Thurs. Sept 7: all day

Thank you, and I look forward to talking.

Best regards,

Brad Glenn, Ph.D.
Federal Regulatory Affairs Manager
Environmental Science Business

Bayer: Science for a Better Life

Bayer U.S. LLC
2 T.W. Alexander Dr.
Research Triangle Park
Durham, NC 27709 United States
WWW-B-1140-02

CropScience Division
Tel: +1 919 549-3958
Mobile: +1 919 475-7629
E-mail: brad.glenn@bayer.com
Web: <http://www.bayer.com>

From: Arrington, Linda [<mailto:Arrington.Linda@epa.gov>]
Sent: Tuesday, August 15, 2017 5:11 PM
To: Terrie Moore
Cc: Karen Shearer; Brad Glenn; BCSReg_Archive
Subject: RE: Fosetyl-AI Label Mitigations

Hi Terri,

Let me check their schedule and will get back to you.

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Tuesday, August 15, 2017 3:40 PM
To: Arrington, Linda <Arrington.Linda@epa.gov>
Cc: Karen Shearer <karen.shearer@bayer.com>; Brad Glenn <brad.glenn@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: Fosetyl-AI Label Mitigations

Hi Linda,

I apologize for not getting back to you sooner. I am transitioning to a new role and also had some difficulties getting schedules aligned for an internal discussion.

I have discussed internally and we were wondering if we could have a meeting with several folks at the Agency to discuss the implications of the Interim Decision language. We were hoping to have you, Ricardo, and the Product Manager and Branch Chief from RD for Fosetyl-AI (Shaja Joyner and Rachel Holloman). I have listed below some possible times for us which will include my manager (Karen Shearer), my replacement (Brad Glenn), and me. Hopefully one of these times will work for all of you. If not then I can try to propose some other times for a meeting. Thank you and have a great day!

Mon Aug. 21: 3 – 5 pm
Mon. Aug. 28: 11am – 5 pm
Tues. Sept 5: 1 – 5 pm
Wed. Sept 6: 1 – 5 pm
Thurs. Sept 7: all day

Best regards,

Terrie Moore, Ph.D.
Regulatory Affairs Manager



Science For A Better Life

Bayer U.S. LLC
CropScience Division
Regulatory Affairs
2 TW Alexander Dr
RTP, NC 27703 USA

Tel +1 919 549 5678
Fax
Mobile +1 919 491 0708
E-mail terrie.moore@bayer.com
Web <http://www.bayer.com>

From: Terrie Moore
Sent: Wednesday, August 09, 2017 12:55 PM
To: 'Arrington, Linda'
Cc: BCSReg_Archive
Subject: RE: Fosetyl-AI Label Mitigations

Thanks for your reply Linda! I will have some discussions internally on the wording and path forward

Have a great day!

Best regards,
Terrie

From: Arrington, Linda [<mailto:Arrington.Linda@epa.gov>]
Sent: Tuesday, August 08, 2017 2:46 PM
To: Terrie Moore
Cc: BCSReg_Archive; BCSReg_Archive
Subject: RE: Fosetyl-AI Label Mitigations

Hi Terrie,

You were next on my list of people to talk to today. PRD, including Ricardo, and RD spoke last week about the labels and the language you proposed instead of the language in the ID. We both agreed that the language in the ID must be used on the label which is keeping with the intent of the risk assessment. However we have no objection with you including language you feel will ensure that no more than 11 applications of the product are applied. Please submit your updated labels with the language from the ID to me.

Thanks,

Linda Arrington, Branch Chief
RMIB 5
Pesticide Re-evaluation Division
Office 703 305 6249
Fax 703 308 8005

From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Tuesday, August 08, 2017 2:25 PM

To: Arrington, Linda <Arrington.Linda@epa.gov>
Cc: BCSReg_Archive <esepamailbox@bayer.com>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: Fosetyl-AI Label Mitigations

Hi Linda,

We spoke a few weeks ago about the statements on our Fosetyl-AI labels. I was following up to see if you had any discussions with Ricardo on the yearly maximum statements. Please let me know if you would like to discuss or have any other questions.

Thank you and have a great day!

Best regards,

Terrie Moore, Ph.D.
Regulatory Affairs Manager



Science For A Better Life

Bayer U.S., LLC
CropScience Division
Regulatory Affairs
2 TW Alexander Dr
RTP, NC 27703, USA

Tel +1 919 549 5678
Fax
Mobile +1 919 491 0708
E-mail terrie.moore@bayer.com
Web <http://www.bayer.com>

From: Terrie Moore
Sent: Thursday, July 20, 2017 2:16 PM
To: 'Arrington.Linda@epa.gov'
Cc: BCSReg_Archive
Subject: Fosetyl-AI Label Mitigations

Hi Linda,

I was hoping to discuss the Fosetyl-AI label mitigations with you, but I wanted to provide some information that I am hoping will be useful for our discussion. I have created a table (below) with the different rates on the 2 fosetyl-AI products we have.

The wording we have on the label for the maximum use rate per year was submitted to Ricardo Jones when he was the relevant CRM and he had indicated this language acceptable as we would be at the same limit that Risk Assessments were performed with. One of the main reasons that we would like to state the maximum amount of AI is that it would be easier for users to track how much they use especially if they use different products containing fosetyl-AI. This is especially important in the turf area where multiple products may be used containing the same ai. The wording we submitted to Ricardo and currently on the submitted labels is the following

- On 432-890 it states
"Do not exceed a total of 180 lb of product per acre, per crop, per year " – for ornamentals
"Do not exceed a total of 180 lbs of product per acre, per year." – for turf
- On 432-1541 it states
"Do not exceed a total of 240 lb of product per acre, per year."

If you take a look at the rate comparisons below (and in attached excel doc), you can see that the different rates would mean different amounts being applied and this would not be consistent label to label. We would get a lot of questions from users on why a product with lower ai content would not be given the same yearly maximum as a product with a higher ai content. This could drive people to use higher rates knowing that they are limited in the number applications vs. the amount of ai applied. This is not a situation that we would want.

I am also very concerned about the line that I highlighted at the 8 oz rate of 432-890. 11 applications at this rate would go over the 144 lbs ai/A that Risk Assessments were done with during Registration Review. We want to be good stewards of our products and do not want users applying over the amount used for Risk Assessments. I am hoping that we could discuss the wording for the label mitigations. Would you be available anytime this afternoon or sometime tomorrow?

Reg. Number	Product	Crop	Rate (oz/1000 sq ft)	Rate lbs/A	# of Applications per year (144 lbs/A)	lbs/A If 11 apps	Application Method
432-890	Chipco Signature	Turf	4	8.695652174	16.56	95.65217	Foiliar
432-890	Chipco Signature	Turf	6	13.04347826	11.04	143.4783	Foiliar
432-890	Chipco Signature	Turf	8	17.39130435	8.28	191.3043	Foiliar
432-1541	Signature Xtra	Turf	2	3.260869565	44.16	35.86957	Foiliar
432-1541	Signature Xtra	Turf	4	6.52173913	22.08	71.73913	Foiliar
432-1541	Signature Xtra	Turf	6	9.782608696	14.72	107.6087	Foiliar

Reg. Number	Product	Crop	Rate (lbs/100 gal)	Rate lbs/A	# of Applications per year (144 lbs/A)	lbs/A If 11 apps	Application Method
432-890	Chipco Signature	Ornamentals	1.25	1.25	115.2	13.75	Foiliar
432-890	Chipco Signature	Ornamentals	2.5	2.5	57.6	27.5	Foiliar
432-890	Chipco Signature	Ornamentals	5	5	28.8	55	Foiliar

Thank you and have a great day!

Best regards,

Terrie Moore, Ph.D.
Regulatory Affairs Manager



Science For A Better Life

Bayer U.S. LLC
CropScience Division
Environmental Science Division
Regulatory Affairs
2 TW Alexander Dr.

Tel: +1 919 549 5678
Fax:
Mobile: +1 919 491 0708
E-mail: terrie.moore@bayer.com
Web: <http://www.bayer.com>

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Balan, Aswathy

From: Balan, Aswathy
Sent: Monday, May 22, 2017 1:12 PM
To: Inouye, John@CDPR
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Thanks John for confirming.

Enjoy your rest of the day!

Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
DC SPP OPP RD
Environmental Protection Agency
Ph: 703-347-0510

From: Inouye, John@CDPR [mailto:John.Inouye@cdpr.ca.gov]
Sent: Monday, May 22, 2017 12:37 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Aswathy-

We denied registration of the product on September 8, 2016. So far we haven't heard anything from the registrant.

Sincerely,

John E. Inouye
Senior Environmental Scientist
Pesticide Registration Branch
(916) 324-3538
E-mail: John.Inouye@cdpr.ca.gov

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]
Sent: Monday, May 22, 2017 9:11 AM
To: Inouye, John@CDPR
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Hi John,

Hope you are keeping well. We are still pursuing the misleading claims on the fosetyl-al product label and noticed that the registrant sent us a revised label with certain claims removed indicating per CDPR request. However, at our last communication, you mentioned CDPR did not grant registration of this product. Has there been any change since then?

Thanks,

S: 1000646

Milestone Email: terrie.moore@bayer.com

Regulatory Type: Product Registration - Section 3



Resubmission

Yes ☐ No ☒

Application Type: Amendment



Fee For Service

Yes ☐ No ☒

Billable

Yes ☐ No ☐

Company: 432 BAYER ENVIRONMENTAL SCIENCE



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 20



Product #: 432-1541

Product Name: 12ESP705 FUNGICIDE

Overridden

Me Too
Section3:

Me Too Product
Name:

Application Date: 13-Mar-2017



OPP Rec'd Date: 13-Mar-2017



Front End Date: 15-Mar-2017



Risk Manager Send Date: 16-Mar-2017



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track

New Ingredient:

Receipt Description:

Portal submission pkg #18051 Submission of data to support plant health claims

New Ingredient

Request Date

New Ingredient

Receipt Date

Form A

Signature Date

Form B

Signature Date

Receipt Content

Study

View/Edit



March 15, 2017

Ms. Shaja Joyner
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
211 W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: **432-1541 12ESP705 Fungicide:** Submission of Plant Health Article

Dear Ms. Joyner,

Environmental Science, a division of Bayer CropScience would like to submit an article to support the plant health claims on the 13ESP705 (432-1541) label as requested by the Agency.

The article citation is shown below:

Huang, B. and Liu, X. Physiological Responses of Creeping Bentgrass to Heat Stress Affected by Phosphonate Fungicide Application. International Turfgrass Society, Volume 11, 2009. 799-806.

Enclosed with this letter are the following documents:

- Application form 8570-1
- Transmittal Document
- Submission Data Matrix for 13ESP705
- Article from International Turfgrass Society

If you have any questions or would like to discuss, please contact me at (919) 549-5678 or email me at terrie.moore@bayer.com.

Sincerely,

Terrie Moore
Regulatory Affairs Manager



M-582647-01-1



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1541	2. EPA Product Manager Shaja Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 12ESP705 Fungicide	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience, Environmental Science division 2 T.W. Alexander Drive, RTP, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of article to support plant health claims as requested by the Agency.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Terrie Moore		Title Regulatory Affairs Manager		Telephone No. (Include Area Code) 919-549-5678	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) M-582645-01-1
2. Signature 		3. Title Regulatory Affairs Manager			
4. Typed Name Terrie Moore		5. Date 3/15/17			

**TRANSMITTAL DOCUMENT****432-1541 Signature Xtra Stressgard****ES-REG-OPPTS-USA-D-014205****Transmittal Date**

March 15, 2017

A handwritten signature in black ink, appearing to be "Terrie Moore".

Company Official:**Company Name:**

Bayer Environmental Science

Company Contact:

Moore, Terrie

Company Telephone:

(919) 549-5678

Bayer Environmental Science
2 T.W. Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America



M-582649-01-1

BIBLIOGRAPHY OF SUBMITTED DATA

Study No.	Study	Guideline No.	EPA MRID No.
RPT Study Reports			
Non-Guideline Study Reports			
1	Huang, B.; Liu, X.; Physiological responses of creeping bentgrass to heat stress affected by phosphonate fungicide application; Department of Plant Biology and Pathology, Rutgers University, New Brunswick, NJ, USA; Report No.: M-582063-01-1; Document No.: M-582063-01-1; 2009-12-31; Pages: 11	NG	49055801 50267901

Balan, Aswathy

From: Terrie Moore <terrie.moore@bayer.com>
Sent: Tuesday, May 02, 2017 10:56 AM
To: Balan, Aswathy
Cc: BCSReg_Archive
Subject: [WARNING: SPF validation failed] RE: 12ESP705 (432-1541) -Fosetyl-al

Thank you for letting me know! I will ask our archivist to update our records.

Have a great day!

Best regards,
Terrie

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]
Sent: Tuesday, May 02, 2017 8:31 AM
To: Terrie Moore
Subject: RE: 12ESP705 (432-1541) -Fosetyl-al

Hi Terrie,

Just wanted to inform you that a new MRID 50267901 has been assigned to the study you submitted. There was a mix-up with another submission, so we had to reassign the MRID for this one.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OC'SPP/OPPRD
Environmental Protection Agency
Ph: 703-347-0510

From: Terrie Moore [mailto:terrie.moore@bayer.com]
Sent: Wednesday, March 15, 2017 11:49 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: Joyner, Shaja <Joyner.Shaja@epa.gov>; Holloman, Rachel <Holloman.Rachel@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: 12ESP705 (432-1541) -Fosetyl-al

Hi Aswathy,

I wanted to let you know that the submission was completed on Mon. (3/13/16). I have attached the confirmation email from the Portal here. Please let me know if you have any questions.

Thank you and have a great day!

Best regards,
Terrie

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Friday, March 10, 2017 11:31 AM
To: Terrie Moore
Cc: BCSReg_Archive; Joyner, Shaja; Holloman, Rachel
Subject: RE: 12ESP705 (432-1541) -Fosetyl-al

Thanks for the update Terrie.

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Friday, March 10, 2017 11:01 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: 12ESP705 (432-1541)

Hi Aswathy,

Our lawyer came back and cleared us for submission at the beginning of week. So I have prepared the submission documents and they will be uploaded into our archival system and then submitted by our Regulatory Archivist next week. I have on my documents a target date of Mar. 15 and expect the article to be submitted next Wed. I will follow up with you when I get confirmation that it was submitted. Thank you for being so patient with us! It was more red tape than I have dealt with before.

Thank you and have a great weekend!

Best regards,
Terrie

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Wednesday, March 08, 2017 2:23 PM
To: Terrie Moore
Cc: Holloman, Rachel; Joyner, Shaja
Subject: RE: 12ESP705 (432-1541)

Hi Terrie,

Just following up to see if you have any update on when you make the submission.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

Balan, Aswathy

From: Kish, Tony
Sent: Wednesday, February 08, 2017 5:10 PM
To: Holloman, Rachel; Balan, Aswathy; Joyner, Shaja
Cc: Giles-Parker, Cynthia; Johnson, Hope; Garvie, Heather
Subject: RE: Fosetyl-Al -misleading plant health claims on label

Rachel- I'm not working on anything now but we need both FHB and FB inputs on the revisions to assure consistency where these over-the-top claims might be sought on other labels.

From: Holloman, Rachel
Sent: Wednesday, February 08, 2017 4:48 PM
To: Kish, Tony <Kish.Tony@epa.gov>; Balan, Aswathy <Balan.Aswathy@epa.gov>; Joyner, Shaja <Joyner.Shaja@epa.gov>
Cc: Giles-Parker, Cynthia <Giles-Parker.Cynthia@epa.gov>; Johnson, Hope <Johnson.Hope@epa.gov>; Garvie, Heather <Garvie.Heather@epa.gov>
Subject: RE: Fosetyl-Al -misleading plant health claims on label

Tony, The link below is to the approved label that we discussed. California expressed their concern with several of the claims made on this label. We met with you and OGC to discuss the claims. Since then, California denied their state registration and identified the claims that we agreed were false and misleading. The company has informally submitted some documentation in support of some of their claims. Once an official submission has been made, we will seek review from BEAD to determine what needs to be removed, modified or left alone. Are you currently working with an action involving this chemical? Thanks! Rachel

From: Kish, Tony
Sent: Wednesday, February 08, 2017 4:10 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>; Joyner, Shaja <Joyner.Shaja@epa.gov>; Holloman, Rachel <Holloman.Rachel@epa.gov>
Cc: Giles-Parker, Cynthia <Giles-Parker.Cynthia@epa.gov>; Johnson, Hope <Johnson.Hope@epa.gov>; Garvie, Heather <Garvie.Heather@epa.gov>
Subject: RE: Fosetyl-Al -misleading plant health claims on label

We met on this 9/30/15 and I thought we agreed the plant health/stress management claims in highlighted attachment were either removed or clearly qualified using "may" or similar because otherwise they are considered claims which happen 100% of the time which are false and misleading. Now I see they are approved in label link below? I know we did not want to review the 800 page efficacy study. These claims open up a whole new door that we do not want on labels.

<< File: 432-1541-20150306. highlighted.pdf >>

https://www3.epa.gov/pesticides/chem_search/ppls/000432-01541-20150306.pdf

Balan, Aswathy

From: Balan, Aswathy
Sent: Friday, February 03, 2017 11:41 AM
To: Holloman, Rachel
Cc: Joyner, Shaja
Subject: RE: 12ESP705 (432-1541)

Yes, I have asked Terrie Moore to make an official submission (so that I can bean to BEAD).

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OC'SPP OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Holloman, Rachel
Sent: Friday, February 03, 2017 11:39 AM
To: Joyner, Shaja <Joyner.Shaja@epa.gov>; Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: 12ESP705 (432-1541)

Just want to make sure that we are moving forward with beaning this to BEAD. Given the document that we received from the registrant, we have enough to move forward.

From: Joyner, Shaja
Sent: Friday, February 03, 2017 11:29 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: Holloman, Rachel <Holloman.Rachel@epa.gov>
Subject: Re: 12ESP705 (432-1541)

Ok

Sent from my iPhone

On Jan 31, 2017, at 3:06 PM, Balan, Aswathy <Balan.Aswathy@epa.gov> wrote:

Shaja,

Rachel told me to hold off from checking with BEAD since they said they do not want to review any efficacy data. She said she will check with Dan/Mike and get back to us.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OC'SPP OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Joyner, Shaja
Sent: Tuesday, January 31, 2017 1:44 PM

To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: Holloman, Rachel <Holloman.Rachel@epa.gov>
Subject: RE: 12ESP705 (432-1541)

Ok, let's see if it's possible to get his feedback prior to meeting.

Thanks!

From: Balan, Aswathy
Sent: Tuesday, January 31, 2017 1:35 PM
To: Joyner, Shaja <Joyner.Shaja@epa.gov>
Cc: Holloman, Rachel <Holloman.Rachel@epa.gov>
Subject: RE: 12ESP705 (432-1541)

Yeah sure, I will schedule a meeting for this Friday.

Also from what I can recall, Tara did not help us on this one, it was somebody else in Skee's team, I can't remember the name exactly but I think someone named Leonard.

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RED
Environmental Protection Agency
Ph. 703-347-0510

From: Joyner, Shaja
Sent: Tuesday, January 31, 2017 1:25 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: Holloman, Rachel <Holloman.Rachel@epa.gov>
Subject: FW: 12ESP705 (432-1541)

Hi Aswathy- I'm just getting an opportunity to read this. Could you put a meeting on the calendar for Friday since Rachel will be in the office? In the meantime, let's see if we can get "unofficial" input from BEAD. I believe Tara weighted in on this in the beginning. Let me know if this is possible.

Thanks.

From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Monday, January 30, 2017 3:43 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Cc: Joyner, Shaja <Joyner.Shaja@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: 12ESP705 (432-1541)

Hi Aswathy and Shaja,

Thank you for allowing us the time to look into your concerns with the plant health claims on the 12ESP705 (432-1541) label. Here are a few points I would like to discuss with you:

- Our Product Development Manager has confirmed that 12ESP705 is not a plant growth regulator. It is actually a plant health promoter. Also, in the efficacy data that we submitted last year, the report with the Title "Document Supporting the Claims for Abiotic stress from

traffic, aeration equipment and phytotoxicity from turf growth regulators on the Signature Xtra Stressgard label" has specific data on the how 12ESP705 (Signature Xtra) helps turf recover from the effects of plant growth regulators.

- For the anti-oxidant claims, I would like to give a reference for peer-reviewed journal article that shows evidence that fosetyl-Al inhibits oxidation and therefore has properties that are consistent with anti-oxidants. I have attached the article with the relevant information highlighted.
- For the winter cold injury claims, we have some new data that we could submit from 2016 if you would like to review the data.

Here are some of the times I am free this week and hopefully we can find something that could work for all of us.

- Wed. Feb 1: after 11pm
- Thurs. Feb 2: 9-11am and 3-4pm
- Fri. Feb. 3: 10-11am

Please let me know what time you would like to discuss.

Thank you and have a great day!

Best regards,

Terrie Moore, Ph.D.
Regulatory Affairs Manager



Science For A Better Life

Bayer U.S. LLC
CropScience Division
Environmental Science Division
Regulatory Affairs
2 TW Alexander Dr
RTP, NC 27703 USA

Tel: +1 919 549 5678
Fax:
Mobile +1 919 491 0708
E-mail terrie.moore@bayer.com
Web: <http://www.bayer.com>

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Wednesday, January 04, 2017 1:02 PM
To: Terrie Moore
Cc: Joyner, Shaja
Subject: RE: 12ESP705 (432-1541)

Hi Terrie,

Please do not submit any data related to our label revision request to the Agency at this time. We will wait on your feedback from consultation with your Product Development Manager on those claims.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP RD
Environmental Protection Agency
Ph: 703-347-0510

From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Monday, December 19, 2016 11:31 AM
To: Joyner, Shaja <Joyner.Shaja@epa.gov>
Cc: Balan, Aswathy <Balan.Aswathy@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: 12ESP705 (432-1541)

Hi Shaja and Aswathy,

I have asked our Product Development Manager about the 3 claims that you had questions on. He is out of the country for the remainder of the year, so I am waiting for his reply. I have also asked that he finish up the report for the last year's trials so that could be submitted to you as soon as possible. I think we should be able to submit the new data in Jan.

I was also wondering since I just submitted Registration Review changes in Oct. this year, if the actions could be rolled in together to prevent having multiple label changes that need to be implemented with different obsolete dates? This would make the label change less complicated. Also in the changes that I submitted for Registration Review, I also submitted changes that CDPR wanted for our label claims, but the 3 that you pointed out were not the ones that they felt we lacked data for. Do you think it would be possible to keep the actions together? Thank you!

Happy Holidays!

Best regards,

Terrie Moore, Ph.D.
Regulatory Affairs Manager



Science For A Better Life

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Environmental Science
BCS-NA-RA, Regulatory Affairs
2 TW Alexander Dr.
RTP, NC 27703, USA

Tel: +1 919 549 5678
Fax:
Mobile: +1 919 491 0708
E-mail: terrie.moore@bayer.com
Web: <http://www.bayer.com>

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Balan, Aswathy

From: Balan, Aswathy
Sent: Wednesday, January 04, 2017 9:49 AM
To: Joyner, Shaja
Subject: RE: 12ESP705 (432-1541)

Okay. I will check with Ricardo how far along he is on this one.

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Joyner, Shaja
Sent: Wednesday, January 04, 2017 9:41 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: 12ESP705 (432-1541)

Correct we don't want more data. However, I'm not sure where PRD is with respect to wrapping up their process. If they anticipate submitting in the near future, then I suppose we can wait and do one review. If not, we should just ask for the same label that was submitted to PRD and review for approval so that we can close out this action.

From: Balan, Aswathy
Sent: Wednesday, January 04, 2017 9:23 AM
To: Joyner, Shaja <Joyner.Shaja@epa.gov>
Subject: FW: 12ESP705 (432-1541)

Hi Shaja,

Missed to check with you how we should handle Terrie's email below. I presume we don't want her to submit any more data?

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Monday, December 19, 2016 11:31 AM
To: Joyner, Shaja <Joyner.Shaja@epa.gov>
Cc: Balan, Aswathy <Balan.Aswathy@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: 12ESP705 (432-1541)

Hi Shaja and Aswathy,

I have asked our Product Development Manager about the 3 claims that you had questions on. He is out of the country for the remainder of the year, so I am waiting for his reply. I have also asked that he finish up the report for the last year's trials so that could be submitted to you as soon as possible. I think we should be able to submit the new data in Jan.

I was also wondering since I just submitted Registration Review changes in Oct. this year, if the actions could be rolled in together to prevent having multiple label changes that need to be implemented with different obsolete dates? This would make the label change less complicated. Also in the changes that I submitted for Registration Review, I also submitted changes that CDPR wanted for our label claims, but the 3 that you pointed out were not the ones that they felt we lacked data for. Do you think it would be possible to keep the actions together? Thank you!

Happy Holidays!

Best regards,

Terrie Moore, Ph.D.
Regulatory Affairs Manager



Science For A Better Life

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Environmental Science
BCS-NA-RA, Regulatory Affairs
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Mobile: +1 919 491 0708
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Web: <http://www.bayer.com>

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Balan, Aswathy

From: Balan, Aswathy
Sent: Tuesday, November 01, 2016 2:35 PM
To: Koch, Erin
Subject: misleading/misbranding plant health claims on label
Attachments: CDPR memo.pdf; New P 432-1541 12ESP705 Fungicide 10-07-2015, 09-23-2016, 09-27-2016_sha....pdf

Hi Erin,

Couple of months back, actually last year, we had talked to you on a Fosetyl –AI product label [12ESP705 Fungicide (Reg# 432-1541)] with numerous plant health claims which are misleading/misbranding, brought to our attention by CDPR.

After discussion with you, we asked the registrant to submit efficacy data in support of those claims. Due to resource constraints (within BEAD) we were unable to review the data they submitted. However, CDPR reviewed the same data and provided us their memo (attached).

We also had a meeting with OECA last week to get their thoughts and they do agree we should go forward and ask the registrant to remove those claims.

The registrant has submitted a label fast track amendment last month (Oct 7, 2016) to the Agency, in response to the changes requested per Registration Review for Fosetyl-AI. Along with those changes, they have deleted a couple of these questionable claims (their cover letter says per CDPR request). However, some are still present on the label and we would like to get your input on the next steps.

I am attaching a highlighted copy of the label for your review. The claims being deleted by the registrant along with the pending reg review action are the green highlights with red strikeout and the plant health claim sections that are still questionable are the highlights in yellow (pages 4 and 5).

I will send a calendar invite for this week following this email.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OC'SPP (OPPRD)
Environmental Protection Agency
Ph: 703-347-0510

Balan, Aswathy

From: Miles, James
Sent: Tuesday, October 18, 2016 4:10 PM
To: Balan, Aswathy
Cc: Holloman, Rachel; Joyner, Shaja; Hellyer, Yvette; Varco, Joseph
Subject: RE: Misleading/Misbranding plant health claims (Reg# 432-1541)

Thank you, we'll look into this and speak to you next week.

From: Balan, Aswathy
Sent: Tuesday, October 18, 2016 2:42 PM
To: Miles, James <miles.james@epa.gov>
Cc: Holloman, Rachel <Holloman.Rachel@epa.gov>; Joyner, Shaja <Joyner.Shaja@epa.gov>
Subject: Misleading/Misbranding plant health claims (Reg# 432-1541)

Hi James,

We would like to get your thoughts on a Fosetyl –AI product label with numerous plant health claims which was brought to our attention by CDPR.

CDPR pointed out to us late last year, that the label for the product 12ESP705 Fungicide (Reg# 432-1541), that EPA registered in March 2015, contains certain plant health claims which are misleading/misbranding. Based on this, we asked the registrant to submit efficacy data in support of those claims. Due to resource constraints we were unable to review the data they submitted. However, CDPR reviewed the same data and provided us their memo (attached).

We were having internal discussions on the next steps and about contacting you, when we noticed that the registrant submitted a revised label this month (Oct 7, 2016) to the Agency, in response to the changes requested per Registration Review for Fosetyl-AI. Along with changes requested per Reg Review, they have deleted a couple of those questionable claims (their cover letter says per CDPR request). However, some are still present on the label and we would like you to take a look at that label and provide any guidance.

I am attaching a highlighted copy of the label for your review. The claims being deleted by the registrant along with the pending reg review action are the green highlights with red strikeout and the plant health claim sections we would like you to review are the highlights in yellow (pages 4 and 5).

We would like to set up a meeting with you next week if possible. I will send a calendar invite following this email. If you need to look at the study or need any additional information, please let me know.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RI
Environmental Protection Agency
Ph: 703 347-0510



October 7, 2016

Mr. Ricardo Jones
U.S. Environmental Protection Agency
Pesticide Re-evaluation Division (7508P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: Label Changes for Fosetyl-AI Registration Review (EPA-HQ-OPP-2007-0379)

Dear Mr. Jones,

Environmental Science, a division of Bayer CropScience would like to submit a label change for 2 Fosetyl-AI labels: Aliette WDG (432-890) and 13ESP705 (432-1541). There are 2 other Fosetyl-AI that we would like to cancel: Chipco Aliette WSP (432-894) and Aliette HG (432-897). These 2 products will be canceled at the renewal period at the end of 2016.

The changes on the labels Aliette WDG (432-890) and 13ESP705 (432-1541) are required by the Fosetyl-AI Interim Registration Review Decision (EPA-HQ-OPP-2007-0379) and follow the format of the proposed label for Aliette WDG (432-890) that was sent to the Agency for review. The Memorandum dated February 27, 2013 (PC code 123301) is attached to this submission for your reference.

In addition to the required changes, we made several changes on the 13ESP705 (432-1541) to satisfy CDPR requests. These changes include:

- Deleted – "that alleviates stress from both abiotic and biotic sources"
- Deleted – "high wilt potential" and "injury from disease"
- Deleted – Entire tank mix section

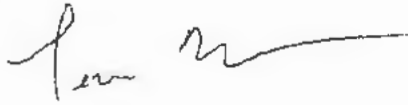
We also would like to request that you to take into consideration an 18 month label transition period after this label change is approved by the Agency. The 18 month time period would allow time for state submissions and approvals which for some states can take 6-12 months or longer.

Enclosed with this submission are the following documents:

- 8570-1 form
- 2 copies of each label including shaded labels for 432-890 and 432-1541
- Memorandum dated February 27, 2013 (PC code 123301)

If you have any questions, contact me at (919) 549-5678 or email me at terrie.moore@bayer.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Terrie Moore', with a long horizontal flourish extending to the right.

Terrie Moore
Regulatory Affairs Manager

GROUP	33	FUNGICIDE
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12ESP705 FUNGICIDE

ABNS: Signature Xtra Stressgard , Chipco Signature Xtra Stressgard, Signature Xtra

A plant health promoting systemic fungicide. ~~that alleviates stress from both abiotic and biotic sources.~~

ACTIVE INGREDIENT:

Aluminum tris (O-ethyl phosphonate):.....60.00%

OTHER INGREDIENTS:.....40.00%

TOTAL:.....100.0%

EPA Reg. No. 432-1541

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION

For MEDICAL and TRANSPDRATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-800-331-2867

Net Contents:

PRODUCED FOR



Bayer Environmental Science

A Division of Bayer CropScience, LP
PO Box 12014 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything to an unconscious person.
If in eyes:	<ul style="list-style-type: none"> • Hold eyes open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of medical emergency for additional information call toll free 1-800-334-7577	
NOTE TO PHYSICIAN: Treat symptomatically	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

- Harmful if swallowed.
- Causes moderate eye irritation
- Avoid contact with eyes or clothing
- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE):

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks
- Chemical-resistant (such as natural rubber) gloves (if more options are needed, follow the instructions for category A on an EPA chemical-resistance category selection chart).

Engineering Controls:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
<p>Users should:</p> <ul style="list-style-type: none"> • Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. • Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. • Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters.

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

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DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12-24 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- coveralls over long-sleeved shirt and long pants,
- socks and shoes,
- chemical-resistant gloves made of any of any waterproof material such as natural rubber \geq 14 mils.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter allow others to enter the treated area until sprays have dried.

PRODUCT INFORMATION

12ESP705 FUNGICIDE is a plant health promoting systemic fungicide. ~~that alleviates stress from both abiotic and biotic sources~~

For use on:

- Turf on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites.

PLANT HEALTH

12ESP705 FUNGICIDE when applied at the prescribed rates and intervals promotes healthier roots, increases plant drought tolerance, and improves plant water utilization. This leads to a reduction in the need for hand watering and a general saving of water use. The resulting improvement in function of these healthier roots leads to more efficient uptake of plant nutrients improving cell turgidity and results in a healthier and sturdier plant structure reducing the impact of traffic or mechanical damage. These effects are consistent with the properties of anti-oxidants. A property of **12ESP705 FUNGICIDE** is to act as an inducer of systemic resistance in plants resulting in production of plant metabolites responsible for maintaining plant processes.

Cool season grasses such as tall fescues, bluegrasses and bentgrasses are prone to damage during summer heat and summer decline leading to reduced root mass in the summer months. Turf treated with **12ESP705 FUNGICIDE** retains turf quality through summer stress by alleviating plant stresses, enhancing disease resistance through induced system resistance and protecting the plant from the adverse effects of solar radiation.

Warm season grasses such as bermudagrass and zoysiagrass, influenced by the effects of insufficient sunlight, are prone to losing chlorophyll and premature senescence. **12ESP705 FUNGICIDE** reduces the negative effects of low light conditions, supports earlier spring green up, turf fill in and extends turf quality.

12ESP705 FUNGICIDE when applied in a program with turf growth regulators further enhances the overall quality of the turf.

APPLICATION INFORMATION

12ESP705 FUNGICIDE must be applied as a foliar spray using ground application equipment. Apply in 1 to 5 gallons of spray solution per 1000 sq ft.

This product may cause staining. Avoid off-target sites such as sidewalks, patios, driveways, pavers, or similar materials. Do not enter treated areas until spray has dried. Rinse spray equipment thoroughly with warm water and detergent.

SPRAY MIXING AND COMPATIBILITY

12ESP705 FUNGICIDE may not be chemically compatible with foliar fertilizers or with copper-based fungicides and phytotoxicity may occur. To determine the physical compatibility of **12ESP705 FUNGICIDE** with any other product, use a small container to mix a small amount (e.g. 1 pint) of spray solution, containing all ingredients in the same order and ratio as the anticipated use. If any indication of physical incompatibility develops, do not use this mixture for spraying. Indication of incompatibility usually appears within 5 - 15 minutes after mixing. Read and follow all directions and precautions on this label and on the labels of any products for which a tank mixture is being considered.

PRODUCT USE RESTRICTIONS

- Do not exceed a total of 240 lb of product per acre, per year.
- Do not graze animals on treated turf.
- Do not feed clippings from treated turf to livestock and poultry.
- Apply by ground application equipment only. Do not apply by air unless directed by Supplemental or Special Local Need labeling.

TURF USE DIRECTIONS

12ESP705 FUNGICIDE is a systemic fungicide, which may be used, in a seasonal program for the control of Pythium diseases, such as blight and root rot, and yellow tuft on common turfgrasses on golf courses, sod farms, sport fields,

institutional, municipal, and commercial sites. Apply as a foliar spray, using 1 to 5 gallons of spray solution per 1,000 square feet, as indicated in the table below. Apply with a properly calibrated sprayer. Maintain agitation during spray operations.

When applying use spray nozzles that will deliver fine or larger spray droplets as defined in the American Society of Agricultural and Biological Engineers (ASABE) standard ANSI/ASAE S572.1 (March 2009).

PLANT HEALTH

12ESP705 FUNGICIDE has a plant health component that is used for the prevention or alleviation of stress from solar radiation and other oxidative processes on turfgrasses. Begin preventative applications prior to the occurrence of adverse weather conditions and repeat at prescribed intervals. Use higher rates prior to the onset of severe stress. **12ESP705 FUNGICIDE** does not replace the use of soil amending adjuvants for soil hydrophobicity and must be used in conjunction with best turf management practices.

STRESS MANAGEMENT	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Stresses such as • high solar radiation high wilt potential • winter cold injury* ✓ • hot and humid weather • traffic wear • physical or mechanical damage • Injury from the use of turf growth regulators* injury from disease • reduced mowing heights	2 - 4	7 - 14	Extend application interval beyond 14 days when climatic conditions are less favorable for turf growth. Do not mow or irrigate treated area until sprays have completely dried.
	4 - 6	14 - 21	
*Apply after damage has occurred Do not exceed a total of 240 lb of product per acre, per year.			

APPLICATIONS FOR TURF DISEASES

DISEASE	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Pythium diseases, Yellow tuft	2 - 4	7-14	Begin preventive foliar spray application when conditions first favor disease and repeat at prescribed interval. Use the highest rate for the longer interval. Do not mow or irrigate treated area until sprays have completely dried.
	4 - 6	14 - 21	
Bacterial Wilt	2 - 4	7	Use the more frequent interval when severe symptoms appear.
	6	14	
Do not exceed a total of 240 lb of product per acre, per year.			

USE AS A RESISTANCE MANAGEMENT TOOL

Fosetyl-AI has no history of resistance development in plant pathogenic fungi, include **12ESP705 FUNGICIDE** as a mixture or rotation partner in programs to manage resistance for fungicides with a high risk of resistance to labeled diseases.

TANK MIXTURES

A **12ESP705 FUNGICIDE** program encourages the development of a thick, vigorous turf stand that is better able to tolerate various stresses (heat, humidity, drying winds, traffic etc) that can have a negative effect on turf health. A tank mixture

12ESP705 FUNGICIDE treated turf is better able to resist disease development and suppress the development of other pests such as weeds and algae.

Summer Decline: For control of Summer Decline caused by a complex of *Pythium* and *Rhizoctonia* diseases, **12ESP705 FUNGICIDE** can be tank mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. Do not exceed label dosage rates. This product cannot be mixed with any product containing a label prohibition against sulfurized.

Anthracnose: For improved control of anthracnose **12ESP705 FUNGICIDE** can be tank mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable to anthracnose.

Bentgrass Dead Spot: For control of bentgrass dead spot, **12ESP705 FUNGICIDE** can be tank mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative multi-application program must be started prior to the appearance of the disease and the conditions favorable for development of bentgrass dead spot.

PRODUCT	RATE FL OZ/OZ* PRODUCT/1,000 SQ. FT.	DISEASE	APPLICATION INTERVAL
12ESP705 FUNGICIDE # 26GT™ or Interface Stressgard or Tadan Stressgard or Mirage Stressgard or Daconil Ultra® or Daconil Action® or Fara® Rainshield™	3.0 to 6.0 # 3.0 to 5.0 1.0 to 2.0 or 1.0 to 2.0 or 3.2* or 3.6 or 4.0 to 6.0	Summer Decline (<i>Pythium</i> and <i>Rhizoctonia</i> spp.) and/or Anthracnose (<i>Colletotrichum</i> <i>graminis</i>)	7-14 days
12ESP705 FUNGICIDE # Interface Stressgard or Fara® Rainshield™ or Daconil Ultra®	3.0 to 6.0 # 3.0 to 5.0 or 6.0 or 5.2*	Leaf spots Bermudagrass Decline	7-14 days

Do not exceed a total of 240 lb a.i. product per acre, per year.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store in original container and keep tightly closed when not in use. Store in a cool dry place. Avoid cross-contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticides wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

CONTAINER HANDLING

Rigid Non-refillable Containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable container. Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Non-Seed Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Non-Seed Treatment Products in Non-Refillable Foil outer pouches of Water soluble Packets (WSP)

Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken.

Rigid Non-Refillable containers with capacities smaller or equal to 5 gallons**PLASTIC CONTAINERS:**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.

SOLID Dilutable formulations:

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

Non-Seed Treatment Products in Non-Rigid, Non-refillable Containers = BAGS

Non-refillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

EVALUATION REPORT - PESTICIDE

Date: June 8, 2016

Plant Physiology – Lan-Xin Shi

Product Name : Signature *XTRA* Stressgard
I. D. No. : 270799
Applicant : Bayer Environmental Science
EPA Reg. No. : 432-1541
Document No. : 415-0124 (Parts 1 and 2)
Active Ingredient : Fosetyl-Al (60%)
Use : Fungicide
Registration Action : Section 3 - Product Registration
Area of Review : Efficacy and Phytotoxicity

Registration Specialist : John Inouye

☐ Data/Information Support Registration ☐ Data/Information Support Conditional Registration
☒ Data/Information Do Not Support Registration ☐ No Registration Action Required

Summary:

Bayer Environmental Science requests registration of their product, Signature *XTRA* Stressgard (Signature) for promoting turfgrass health. The label proposes uses in alleviating stresses from both abiotic and biotic sources, including high solar radiation, high wilt potential, winter cold injury, hot and humid weather, traffic wear, physical or mechanical damage, injury from the use of turf growth regulators, injury from disease, and reduced mowing heights. The subject product is a systemic fungicide containing fosetyl-Al as active ingredient. The proposed label rates are in the range of 2-6 oz/1000 ft². Signature is applied as a foliar spray in a seasonal program using ground application equipment.

The applicant submitted turf quality data from trials conducted at label rates in multiple states during 2014 (Document # 415-0124). Untreated controls (UTC) and standards were included for comparison. In some studies, plots were randomized and replicated, and statistical analyses were performed at $\alpha=0.05$. Results suggested that Signature had positive effects on improvement in bentgrass quality during summer, and faster turf recovery from aeration, traffic wear and bacterial etiolation in Arkansas, Massachusetts, Michigan, New Jersey and North Carolina. These data may serve as supportive information.

It should be noted that the marketing claim (on label pages 1, 3 and 7) is overly broad, and some use claims, such as high wilt potential and injury from disease are too vague. Clear definitions and use conditions for stress management claims that are testable, should be added to the proposed label. Additional data are required to demonstrate the efficacy of Signature for alleviating listed stresses. Trials should be conducted in California or under California-like Conditions. Data should be analyzed statistically at 95% confidence interval, in which UTC data must be included to reach sound conclusions.

Conclusion:

Data do not support registration of Signature *XTRA* Stressgard at this time.

Lan-Xin Shi, Ph.D.
Environmental Scientist

Don Antonowich
Senior Environmental Scientist

Balan, Aswathy

From: Inouye, John@CDPR <John.Inouye@cdpr.ca.gov>
Sent: Tuesday, June 14, 2016 3:15 PM
To: Balan, Aswathy
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-AI plant health claims
Attachments: signature.pdf

Attached is our evaluation memo.

John

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]
Sent: Tuesday, June 14, 2016 12:12 PM
To: Inouye, John@CDPR
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-AI plant health claims

Thanks John for the update. Is it possible for you to share a copy of the review with us?

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OC SPP OPP/RD
Environmental Protection Agency
Ph. 703-347-0510

From: Inouye, John@CDPR [mailto:John.Inouye@cdpr.ca.gov]
Sent: Monday, June 13, 2016 1:43 PM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-AI plant health claims

Aswathy-

Sorry it took so long for us to complete our efficacy review. Our evaluator determined the data did not support registration in California and the claims on the label are overly broad and some uses are too vague. Therefore we will be denying California registration.

Sincerely,

John E. Inouye
Senior Environmental Scientist
Pesticide Registration Branch
(916) 324-3538
E-mail: John.Inouye@cdpr.ca.gov

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Wednesday, March 23, 2016 6:33 AM
To: Inouye, John@CDPR
Cc: Joyner, Shaja; Holloman, Rachel
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Thanks for the update John.

Have a nice day!
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP RD
Environmental Protection Agency
Ph: 703-347-0510

From: Inouye, John@CDPR [<mailto:John.Inouye@cdpr.ca.gov>]
Sent: Wednesday, March 23, 2016 9:26 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Good morning Aswathy,

Unfortunately, it's still being reviewed. Due to workload, it's taking a little longer than usual to complete the review.

John

From: Balan, Aswathy [<mailto:Balan.Aswathy@epa.gov>]
Sent: Monday, March 21, 2016 7:23 AM
To: Inouye, John@CDPR
Cc: Joyner, Shaja
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Good morning John!

Hope you had a nice weekend!

Just following up if there are any updates on the efficacy data review of the subject application?

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP RD
Environmental Protection Agency
Ph: 703-347-0510

From: Inouye, John@CDPR [<mailto:John.Inouye@cdpr.ca.gov>]
Sent: Tuesday, January 12, 2016 10:18 AM
To: Balan, Aswathy <Balan.Aswathy@epa.gov>
Subject: RE: Misbranding/ Misleading Statements - Fosetyl-Al plant health claims

Balan, Aswathy

From: Balan, Aswathy
Sent: Monday, March 21, 2016 10:08 AM
To: Jones, Arnet; Becker, Jonathan; Yourman, Leonard
Cc: Joyner, Shaja
Subject: Request closing of bean DP#428596
Attachments: Bean sheet.pdf

Hi BEAD,

Couple of months back (October 2015) RD and BEAD had discussions on a bean I sent for review of plant health efficacy data submitted for product 12ESP705 Fungicide (Reg# 432-1541, active ingredient: Fosetyl-Al). This data was submitted in support of certain misleading claims on the product's label.

However, it was decided at that time that BEAD does not need to move ahead with the review. However, the bean is still open. I request closing of the attached bean (DP#428596).

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OC'SPP OPP RD
Environmental Protection Agency
Ph. 703-547-0510

Balan, Aswathy

From: Inouye, John@CDPR <John.Inouye@cdpr.ca.gov>
Sent: Tuesday, November 10, 2015 11:20 AM
To: Balan, Aswathy
Subject: RE: Misbranding/ Misleading Statements
Attachments: removed.txt

Aswathy –

We currently are reviewing data to see if the claims are acceptable. In the meantime, I'll be available the week of Nov. 16 to discuss these issue with you. Please let me know what day and time.

Sincerely,

John

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]
Sent: Monday, November 09, 2015 11:29 AM
To: Inouye, John@CDPR
Cc: Joyner, Shaja
Subject: RE: Misbranding/ Misleading Statements

Hi John,

EPA would like to have a conference call with Cal DPR to further discuss the Fosetyl-Al plant health claims (432-1541) for which you inquired of the Agency on a few months ago.

Per the Agency's request, efficacy data has been submitted by Bayer. However, upon receipt it was subsequently determined that we no longer have the resources available to perform a full review of the efficacy data by a specialized biologist within our Biological Economical Analysis Division (BEAD), or plant pathologist within the Registration Division (RD). As a result, we have only performed a cursory review of the label claims and the summary portion of the study submitted at the team level within RD.

Therefore, EPA is inquiring as to whether Cal DPR has reviewed the efficacy data submitted by Bayer, and/or if Cal DPR has contacted the registrant with respect to these questionable claims. Also, based on our cursory review, we have a few label comments that we would like to discuss with Cal DPR prior to contacting the registrant.

Please let us know your available dates/time during the week of Nov. 16th, and we will follow-up with a calendar invite for a conference call accordingly.

Best regards,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Joyner, Shaja
Sent: Tuesday, July 14, 2015 12:48 PM
To: Inouye, John@CDPR
Cc: Balan, Aswathy
Subject: RE: Misbranding/ Misleading Statements

Hi John,

Terri Moore, Bayer registration manager sent efficacy data to CAL DPR for the product in question. EPA has now requested the data, but is pending receipt at this time.

Can you confirm that CALDPR is in receipt of the data? If so, will you be reviewing?



SHAJA B. JOYNER

Product Manager 20, Fungicide-Herbicide Branch

United States Environmental Protection Agency

Registration Division / Office of Pesticide Programs

One Potomac Yard

2777 South Crystal Drive, Arlington VA 22202

P: 703.308.3194 E: joyner.shaja@epa.gov F: 703.308.0029

From: Inouye, John@CDPR [<mailto:John.Inouye@cdpr.ca.gov>]
Sent: Tuesday, July 14, 2015 11:48 AM
To: Joyner, Shaja
Subject: FW: Misbranding/ Misleading Statements

Shaja-

I tried to e-mail you the message below, but it didn't go through. Hopefully this one made it. After looking at the e-mail address I used for you, it looks like I used a "g" instead of a "j" in your name. So much for my typing skills.

Sincerely,

John

From: Inouye, John@CDPR
Sent: Tuesday, July 14, 2015 7:33 AM
To: 'balan.aswathy@epa.gov'
Cc: 'joyner.shaga@epa.gov'
Subject: Misbranding/ Misleading Statements

Aswathy-

This e-mail is just a follow up to our telephone conversation this morning. Attached is a copy of the container label with the concerns boxed in red. I would appreciate it if you would consult with Shaja. Again, the label is making some pretty

broad claims that I believe would be considered "False or misleading " under 40 CFR 156.10 (a)(5) and Section 2(q)(1)(A) of FIFRA.

If you determined the statements are acceptable, I would like to know what data was used or how the registrant was able to substantiate the claims to your Agency.

Sincerely,

John E. Inouye
Senior Environmental Scientist
Pesticide Registration Branch
(916) 324-3538
E-mail: John.Inouye@cdpr.ca.gov

Balan, Aswathy

From: Jones, Arnet
Sent: Monday, October 05, 2015 2:47 PM
To: Becker, Jonathan
Cc: Balan, Aswathy; Yourman, Leonard; Holloman, Rachel; Joyner, Shaja
Subject: Re: Plant efficacy data review - Reg# 432-1541 (Fosetyl-AI)

Please include OGC in the discussion. This type of issue has been arising with increasing regularity and it has major resource implications. Thanks.

Sent from my iPhone

On Oct 5, 2015, at 2:32 PM, Becker, Jonathan <Becker.Jonathan@epa.gov> wrote:

Please set up a meeting so we can discuss this further. There are resource constraints in BEAD and I know that Skee will want to than this further.

Thanks,

Jonathan

From: Balan, Aswathy
Sent: Monday, October 05, 2015 2:27 PM
To: Becker, Jonathan; Jones, Arnet; Yourman, Leonard; Holloman, Rachel; Joyner, Shaja
Subject: RE: Plant efficacy data review - Reg# 432-1541 (Fosetyl-AI)

OGC's point of view was that since the registrant has submitted data, we have to check to see what the results tell us in their study and whether it really supports their claims or not.

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP RID
Environmental Protection Agency
Ph: 703-347-0510

From: Becker, Jonathan
Sent: Monday, October 05, 2015 2:11 PM
To: Balan, Aswathy; Jones, Arnet; Yourman, Leonard; Holloman, Rachel; Joyner, Shaja
Subject: RE: Plant efficacy data review - Reg# 432-1541 (Fosetyl-AI)

What was OGC basis for recommending the review of the efficacy data?

Jonathan

-----Original Appointment-----

From: Balan, Aswathy

Sent: Monday, October 05, 2015 2:01 PM

To: Jones, Arnet; Becker, Jonathan; Yourman, Leonard; Holloman, Rachel; Joyner, Shaja

Subject: Plant efficacy data review - Reg# 432-1541 (Fosetyl-Al)

When: Tuesday, October 27, 2015 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomPYS7731E/Potomac-Yard-One

10/5/15

OGC has recommended to go ahead with review of the plant efficacy data submitted by the registrant. Scheduling a meeting towards the end of October to discuss any updates/issues based on the review.

8/11/15

Attached:

1. Bean sent to BEAD for reviewing plant health efficacy data
2. EPA accepted label (stamped March 6, 2015) with the plant health claims highlighted in yellow.

<< File: Bean sheet.pdf >> << File: 432-1541-20150306. highlighted.pdf >>

Study was submitted electronically along with the cover letter, forms, etc. - can be found in Documentum under S# 971565 and MRID = 49618701.

Discuss the review of plant health efficacy data submitted to BEAD for product 12ESP705 Fungicide (Reg# 432-1541, active ingredient: Fosetyl-Al).

Balan, Aswathy

From: Koch, Erin
Sent: Monday, September 21, 2015 2:55 PM
To: Balan, Aswathy
Cc: Joyner, Shaja; Holloman, Rachel
Subject: RE: Fosetyl-Al -misleading claims on label
Attachments: image001.gif

Erin S. Koch
Attorney-Advisor
Pesticides and Toxic Substances Law Office Office of General Counsel USEPA
(202) 564-1718

From: Balan, Aswathy
Sent: Monday, September 21, 2015 12:27 PM
To: Koch, Erin
Cc: Joyner, Shaja; Holloman, Rachel
Subject: Fosetyl-Al -misleading claims on label

Hi Erin,

We would like get your thoughts on a Fosetyl -Al product label with numerous plant health claims.

To provide you a background:

John Inouye of CDPR pointed out to us that the label for the product 12ESP705 Fungicide (Reg# 432-1541) contains certain plant health claims which are misleading/misbranding. Based on this, we asked the registrant to submit efficacy data in support of those claims and we sent to BEAD for review. We had a meeting with BEAD two weeks back and they recommended we consult with OGC before they can start their review.

I am attaching the currently accepted label (March 6, 2015) for this product indicating the misleading claims in yellow highlights.

We met with Bob Perlis briefly, two weeks back to discuss on this issue. He did not give us any specific input but told he will defer this matter to you, not sure whether he got a chance to discuss this subject with you.

I would like to set up a meeting with you next week on Wednesday (9/30), when you come for your weekly visit to RD. Let us know what time would best work for you.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch

Balan, Aswathy

From: Balan, Aswathy
Sent: Tuesday, August 11, 2015 10:28 AM
To: Jones, Arnet
Cc: Joyner, Shaja; Holloman, Rachel; Becker, Jonathan; Yourman, Leonard
Subject: RE: Plant health efficacy data review

Sounds good! I will set up a meeting for the second week of September.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Jones, Arnet
Sent: Tuesday, August 11, 2015 10:22 AM
To: Balan, Aswathy
Cc: Joyner, Shaja; Holloman, Rachel; Becker, Jonathan; Yourman, Leonard
Subject: RE: Plant health efficacy data review

Aswathy – thank you for your message. Len Yourman is the BEAD plant pathologist who works on fosetyl-Al. He will be out of the office for the next 3 weeks, so it will be some time before BEAD can get to this review. I think the best course of action would be for Len to do a quick review of the package after his return on Aug 31st and then to meet with you if there are questions and, most importantly, to discuss the nature and scope of the work and its timeline. I suggest you schedule a meeting for those receiving this message for early September so we can discuss the review.

Thanks, and please let me know if you have questions.
Skee Jones

From: Balan, Aswathy
Sent: Tuesday, August 11, 2015 9:56 AM
To: Jones, Arnet
Cc: Joyner, Shaja; Holloman, Rachel; Becker, Jonathan
Subject: Plant health efficacy data review

Dear Skee,

Attached is the bean for plant health efficacy data for the product 12ESP705 Fungicide (Reg# 432-1541, active ingredient: Fosetyl-Al).

We asked the registrant to submit efficacy data in support of the plant health claims on the label for this product. The cover letter, study, forms, etc. can be found in Documentum – MRID – 49618701 (S# 971565). I am attaching the previously accepted label (March 6, 2015) for this product.

Please review the study at your earliest convenience to see whether the claims are supported by this study. Also please let me know if you have any questions.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
QCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

From: Becker, Jonathan
Sent: Tuesday, August 11, 2015 9:32 AM
To: Balan, Aswathy
Cc: Joyner, Shaja; Holloman, Rachel; Jones, Arnet
Subject: RE: Plant health efficacy data review

Hi Aswathy,

It would be best to send it to Skee (Arnet) Jones and he will assign it to a biologist.

Thanks,
Jonathan

From: Balan, Aswathy
Sent: Tuesday, August 11, 2015 9:14 AM
To: Becker, Jonathan
Cc: Joyner, Shaja; Holloman, Rachel
Subject: Plant health efficacy data review

Hi Jonathan,

I am Aswathy Balan, a reviewer in the Fungicide-Herbicide Branch in RD. We received **plant health efficacy data** from the registrant to support the plant health claims on the label for the product 12ESP705 Fungicide (Reg# 432-1541, active ingredient: Fosetyl-Al). Could you direct me as to whom I should be send this data for review in BEAD.

Thank you for your assistance.

Regards,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
QCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 23, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BAYER ENVIRONMENTAL SCIENCE
2 T. W. ALEXANDER DRIVE
PO.BOX : 12014
RESEARCH TRIANGLE PARK, NC 27709

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 21-JUL-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Bayer CropScience



July 17, 2015

Ms. Shaja Joyner
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: **432-1541 12ESP705 Fungicide:** Submission of Plant Health Efficacy Report

Dear Ms. Joyner,

Bayer Environmental Science (BES) would like to submit a plant health efficacy report to support the plant health claims on the 13ESP705 (432-1541) label as requested by the Agency.

The plant health efficacy report shows summaries and graphs for 22 studies with individual trial reports attached. We believe the data from these studies will support the plant health data claims on the 13ESP705 label.

Enclosed with this letter are the following documents:

- Application form 8570-1
- Transmittal Document
- Submission Data Matrix for 13ESP705
- Plant Health Efficacy Report titled: Document Supporting the Claims for Plant Health and Disease Control on the Signature Xtra Stressgard label (M-512625-01-1).

If you have any questions or would like to discuss, please contact me at (919) 549-5678 or email me at terrie.moore@bayer.com.

Sincerely,

Terrie Moore
Regulatory Affairs Manager

e-Submission



M-527530-01-1

Bayer CropScience

**TRANSMITTAL DOCUMENT**

432-1541 12ESP705 Fungicide

ES-REG-OPPTS-USA-D-012782

Transmittal Date

July 17, 2015

Company Official:

Company Name:

Bayer Environmental Science

Company Contact:

Moore, Terrie

Company Telephone:

+1 919-549-5678

Bayer Environmental Science
2 T.W. Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America



M-527755-01-1

e-Submission

BIBLIOGRAPHY OF SUBMITTED DATA

Study No.	Study	Guideline No.	EPA MRID No.
RPT Study Reports			
Non-Guideline Study Reports			
1	Anon.: Document Supporting the Claims for Plant Health and Disease Control on the Signature Xtra Stressgard label. - not applicable -; Report No.: US0473; Document No.: M-512625-01-1; April 10, 2013; Pages: 815	Non-Guideline	49618701



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1541	2. EPA Product Manager Shaja Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 12ESP705 Fungicide	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience, Environmental Science division 2 T.W. Alexander Drive, RTP, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Plant Health Data as requested by the Agency.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Terrie Moore	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) 919-549-5678	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) M-527529-01-1
2. Signature 	3. Title Regulatory Affairs Manager		
4. Typed Name Terrie Moore	5. Date 7/17/15		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0050; 2070-0057;
2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: July 17, 2015

EPA Reg. No./File Symbol: 432-1541

Page 1 of 1

Applicant=s/Registrant=s Name & Address:

Bayer Environmental Science
2 T.W. Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

Product(s):

432-1541 12ESP705 Fungicide

Ingredient: Fosetyl AL

Guideline Reference
Number

Guideline Study Name

MRID Number

Submitter

Status

Note

RPT Study Reports

Non-Guideline Study Reports

Non-Guideline

Efficacy Data

49618701

Bayer Environmental
Science

OWN

M-512625-01-1 (US0473)
Activity ID: ETFYN002

Signature

Name and Title:
Moore, Terrie – Federal Registration
Manager

Date: July 17, 2015



Balan, Aswathy

From: Balan, Aswathy
Sent: Tuesday, July 14, 2015 12:55 PM
To: 'Terrie Moore'
Cc: Joyner, Shaja
Subject: RE: 12ESP705 FUNGICIDE - EPA Reg# 432-1541

Thanks Terri. We will wait for your submission.

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSPP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0310

From: Terrie Moore [mailto:terrie.moore@bayer.com]
Sent: Tuesday, July 14, 2015 12:20 PM
To: Balan, Aswathy
Cc: Joyner, Shaja; BCSReg_Archive
Subject: RE: 12ESP705 FUNGICIDE - EPA Reg# 432-1541

Hi Ms. Balan,

We do have efficacy data for the plant health claims on 432-1541. This was submitted CDPR for their review and I will prepare a submission to the EPA as well. I will send an electronic submission for the efficacy report and will not send a paper version since the report is over 800 pages. I think we should be able to get this to the Agency by the end of next week. Please let me know if you have any other questions or would like to discuss.

Have a great day!

Best Regards / Freundliche Grüße / Vriendelijke Groeten / Cordialement,

Terrie Moore, Ph.D
Regulatory Affairs Manager



Bayer CropScience

Science For A Better Life

Bayer CropScience LP
Environmental Science
2 TW Alexander Dr., RTP, NC 27709
Tel: +1 919 549 5678
Fax: +1 919
Mobile: +1 919 491-0708
E-mail: terrie.moore@bayer.com

From: Balan, Aswathy [mailto:Balan.Aswathy@epa.gov]
Sent: Tuesday, July 14, 2015 11:12 AM

To: Terrie Moore
Cc: Joyner, Shaja
Subject: 12ESP705 FUNGICIDE - EPA Reg# 432-1541

Good morning Ms. Moore,

I am a reviewer in the Registration Division at OPP, EPA who works along with PM Shaja Joyner. I wanted to raise a concern that was brought to our attention by the Cal DPR regarding a couple of label claims made for the subject product. I have highlighted some statements in the attached label – pages 1, 4 & 5.

We wanted to check with you whether you have any data in place to substantiate the highlighted claims. If present, please submit those data for review else we might have to discuss on making modifications to these claims on the label.

Thanks,
Aswathy

Aswathy Balan, Biologist
Fungicide and Herbicide Branch
OCSP/OPP/RD
Environmental Protection Agency
Ph: 703-347-0510

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

Balan, Aswathy

From: Joyner, Shaja
Sent: Tuesday, July 14, 2015 12:48 PM
To: Inouye, John@CDPR
Cc: Balan, Aswathy
Subject: RE: Misbranding/ Misleading Statements

Hi John,

Terri Moore, Bayer registration manager sent efficacy data to CAL DPR for the product in question. EPA has now requested the data, but is pending receipt at this time.

Can you confirm that CALDPR is in receipt of the data? If so, will you be reviewing?



SHAJA B. JOYNER

Product Manager 20, Fungicide-Herbicide Branch

United States Environmental Protection Agency

Registration Division | Office of Pesticide Programs

One Potomac Yard

2777 South Crystal Drive, Arlington VA 22202

P: 703.308.3194 E: joyner.shaja@epa.gov F: 703.308.0029

From: Inouye, John@CDPR [mailto:John.Inouye@cdpr.ca.gov]
Sent: Tuesday, July 14, 2015 11:48 AM
To: Joyner, Shaja
Subject: FW: Misbranding/ Misleading Statements

Shaja-

I tried to e-mail you the message below, but it didn't go through. Hopefully this one made it. After looking at the e-mail address I used for you, it looks like I used a "g" instead of a "j" in your name. So much for my typing skills.

Sincerely,

John

From: Inouye, John@CDPR
Sent: Tuesday, July 14, 2015 7:33 AM
To: 'balan.aswathy@epa.gov'
Cc: 'joyner.shaga@epa.gov'
Subject: Misbranding/ Misleading Statements

Aswathy-

This e-mail is just a follow up to our telephone conversation this morning. Attached is a copy of the container label with the concerns boxed in red. I would appreciate it if you would consult with Shaja. Again, the label is making some pretty broad claims that I believe would be considered "False or misleading " under 40 CFR 156.10 (a)(5) and Section 2(q)(1)(A) of FIFRA.

If you determined the statements are acceptable, I would like to know what data was used or how the registrant was able to substantiate the claims to your Agency.

Sincerely,

John E. Inouye
Senior Environmental Scientist
Pesticide Registration Branch
(916) 324-3538
E-mail: John.Inouye@cdpr.ca.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 20, 2015

Terrie Moore
Regulatory Affairs Manager
Bayer CropScience
2 T.W. Alexander Dr.
RTP, NC 27709

Subject: Notification per PRN 98-10 – Alternate Brand Names
Product Name: 12ESP705 Fungicide
EPA Registration Number: 432-1541
Application Date: 3/13/2015
Decision Number: 502673

Dear Ms. Moore:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name Signature Xtra Stressgard, Chipco Signature Xtra Stressgard, and Signature Extra has been added to the product record.

If you have any questions, you may contact Angela Hollis at 703 347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Shaja B. Joyner".

Shaja B. Joyner, Product Manager 20
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Bayer CropScience



March 13, 2015

Ms. Shaja Joyner
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room 5-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: **432-1541 12ESP705 Fungicide:** Notification of Alternate Brand Names

Dear Ms. Joyner,

Bayer Environmental Science (BES) would like to submit a notification for alternate brand names (ABNs) of 12ESP705 Fungicide. The ABNs are

- Signature Xtra Stressgard
- Chipco Signature Xtra Stressgard
- Signature Xtra

Enclosed with this letter are the following documents:

- Application form 8570-1.

If you have any questions, please contact me at (919) 549-5678 or email me at terrie.moore@bayer.com.

Sincerely,

Terrie Moore
Regulatory Affairs Manager



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1541	2. EPA Product Manager Shaja Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 12ESP705 Fungicide	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience, Environmental Science division 2 T.W. Alexander Drive, RTP, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

-Notification for Alternate Brand Names (ABNs)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Terrie Moore	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) 919-549-5678
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager	
4. Typed Name Terrie Moore	5. Date 3/13/15	

PROCESSING REQUEST

Reg #: 432 - 1541

Decision #: 493715

Description: New product registration

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated: 3/6/2015

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐ Notification Dated:

☒ New CSF(s) Dated: 5/16/2014

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Aswathy Balan

Division: RD

Phone: 347-0510

Date: 3/9/15



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

432-1541

Date of Issuance:

03/06/2015

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

12ESP705 FUNGICIDE

Name and Address of Registrant (include ZIP Code):

Terrie Moore
Regulatory Affairs Manager
Bayer CropScience, Environmental Science Division,
2 T.W. Alexander Drive, RTP, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c) (7) (A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Shaja B. Joyner, Product Manager 20
Fungicide-Herbicide Branch
Registration Division 7505P

Date:

03/06/2015

2. Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm
3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. The agency will not accept the accelerated studies (54°C for 2 weeks) for these two guidelines. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 432-1541."
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/16/2014

If you have any questions, please contact Aswathy Balan at (703) 347-0510 or balan.aswathy@epa.gov.

GROUP	33	FUNGICIDE
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12ESP705 FUNGICIDE

A plant health promoting systemic fungicide that alleviates stress from both abiotic and biotic sources.

ACTIVE INGREDIENT:

Aluminum tris (O-ethyl phosphonate):.....60.00%

OTHER INGREDIENTS:.....40.00%

TOTAL:.....100.0%

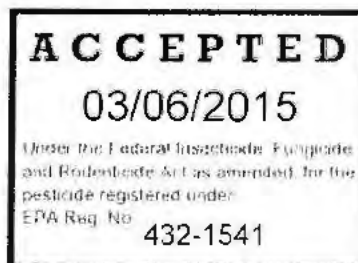
EPA Reg. No. 432-XXXX

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN
CAUTION

For MEDICAL and TRANSPORTATION Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-800-331-2867

Net Contents:



PRODUCED FOR



Bayer Environmental Science

A Division of Bayer CropScience, LP
PO Box 12014 2 T W. Alexander Drive
Research Triangle Park, NC 27709

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Do not induce vomiting unless told to do so by a poison control center or doctor • Have person sip a glass of water if able to swallow • Do not give anything to an unconscious person.
If in eyes	<ul style="list-style-type: none"> • Hold eyes open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice
Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of medical emergency for additional information call toll free 1-800-334-7577	
NOTE TO PHYSICIAN: Treat symptomatically	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

- Harmful if swallowed.
- Causes moderate eye irritation
- Avoid contact with eyes or clothing.
- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE):

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks
- Chemical-resistant (such as natural rubber) gloves (if more options are needed, follow the instructions for category A on an EPA chemical-resistance category selection chart)

Engineering Controls:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
<p>Users should:</p> <ul style="list-style-type: none"> • Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. • Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. • Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing

ENVIRONMENTAL HAZARDS

Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters.

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- coveralls over long-sleeved shirt and long pants,
- socks and shoes,
- chemical-resistant gloves made of any of any waterproof material such as natural rubber ≥ 14 mils

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter or allow others to enter the treated area until sprays have dried.

PRODUCT INFORMATION

12ESP705 FUNGICIDE is a plant health promoting systemic fungicide that alleviates stress from both abiotic and biotic sources.

For use on:

- Turf on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites.

PLANT HEALTH

12ESP705 FUNGICIDE when applied at the prescribed rates and intervals promotes healthier roots, increases plant drought tolerance, and improves plant water utilization. This leads to a reduction in the need for hand watering and a general saving of water use. The resulting improvement in function of these healthier roots leads to more efficient uptake of plant nutrients improving cell turgidity and results in a healthier and sturdier plant structure reducing the impact of traffic or mechanical damage. These effects are consistent with the properties of anti-oxidants. A property of **12ESP705 FUNGICIDE** is to act as an inducer of systemic resistance in plants resulting in production of plant metabolites responsible for maintaining plant processes.

Cool season grasses such as tall fescues, bluegrasses and bentgrasses are prone to damage during summer heat and summer decline leading to reduced root mass in the summer months. Turf treated with **12ESP705 FUNGICIDE** retains turf quality through summer stress by alleviating plant stresses, enhancing disease resistance through induced system resistance and protecting the plant from the adverse effects of solar radiation.

Warm season grasses such as bermudagrass and zoysiagrass, influenced by the effects of insufficient sunlight, are prone to losing chlorophyll and premature senescence. **12ESP705 FUNGICIDE** reduces the negative effects of low light conditions, supports earlier spring green up, turf fill in and extends turf quality.

12ESP705 FUNGICIDE when applied in a program with turf growth regulators further enhances the overall quality of the turf.

APPLICATION INFORMATION

12ESP705 FUNGICIDE must be applied as a foliar spray using ground application equipment. Apply in 1 to 5 gallons of spray solution per 1000 sq ft.

This product may cause staining. Avoid off-target sites such as sidewalks, patios, driveways, pavers, or similar materials. Do not enter treated areas until spray has dried. Rinse spray equipment thoroughly with warm water and detergent.

SPRAY MIXING AND COMPATIBILITY

12ESP705 FUNGICIDE may not be chemically compatible with foliar fertilizers or with copper-based fungicides and phytotoxicity may occur. To determine the physical compatibility of **12ESP705 FUNGICIDE** with any other product, use a small container to mix a small amount (e.g. 1 pint) of spray solution, containing all ingredients in the same order and ratio as the anticipated use. If any indication of physical incompatibility develops, do not use this mixture for spraying. Indication of incompatibility usually appears within 5 - 15 minutes after mixing. Read and follow all directions and precautions on this label and on the labels of any products for which a tank mixture is being considered.

PRODUCT USE RESTRICTIONS

- Do not graze animals on treated turf.
- Do not feed clippings from treated turf to livestock and poultry.

TURF USE DIRECTIONS

12ESP705 FUNGICIDE is a systemic fungicide, which may be used, in a seasonal program for the control of Pythium diseases, such as blight and root rot, and yellow tuft on common turfgrasses on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites. Apply as a foliar spray, using 1 to 5 gallons of spray solution per 1,000 square feet, as indicated in the table below. Apply with a properly calibrated sprayer. Maintain agitation during spray operations.

PLANT HEALTH

12ESP705 FUNGICIDE has a plant health component that is used for the prevention or alleviation of stress from solar radiation and other oxidative processes on turfgrasses. Begin preventative applications prior to the occurrence of adverse weather conditions and repeat at prescribed intervals. Use higher rates prior to the onset of severe stress. **12ESP705 FUNGICIDE** does not replace the use of soil amending adjuvants for soil hydrophobicity and must be used in conjunction with best turf management practices.

STRESS MANAGEMENT	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Stresses such as <ul style="list-style-type: none"> • high solar radiation • high wilt potential • winter cold injury* • hot and humid weather • traffic wear • physical or mechanical damage • injury from the use of turf growth regulators* • injury from disease • reduced mowing heights 	2 - 4	7 - 14	Extend application interval beyond 14 days when climatic conditions are less favorable for turf growth. Do not mow or irrigate treated area until sprays have completely dried.
	4 - 6	14 - 21	

*Apply after damage has occurred

APPLICATIONS FOR TURF DISEASES

DISEASE	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Pythium diseases, Yellow tuft	2 - 4	7-14	Begin preventive foliar spray application when conditions first favor disease and repeat at prescribed interval. Use the highest rate for the longer interval. Do not mow or irrigate treated area until sprays have completely dried.
	4 - 6	14 - 21	
Bacterial Wilt	2 - 4	7	Use the more frequent interval when severe symptoms appear.
	6	14	

USE AS A RESISTANCE MANAGEMENT TOOL

Fosetyl-AI has no history of resistance development in plant pathogenic fungi; include **12ESP705 FUNGICIDE** as a mixture or rotation partner in programs to manage resistance for fungicides with a high risk of resistance to labeled diseases.

TANK MIXTURES

A **12ESP705 FUNGICIDE** program encourages the development of a thick, vigorous turf stand that is better able to tolerate various stresses (heat, humidity, drying winds, traffic etc) that can have a negative effect on turf health. A thick, vigorous **12ESP705 FUNGICIDE** treated turf is better able to resist disease development and suppress the development of other pests such as weeds and algae.

Summer Decline: For control of Summer Decline caused by a complex of Pythium and Rhizoctonia diseases, **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. Do not exceed label dosage rates. This product cannot be mixed with any product containing a label prohibition against such mixing.

Anthracnose: For improved control of anthracnose 12ESP705 FUNGICIDE can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable to anthracnose.

Bentgrass Dead Spot: For control of bentgrass dead spot, 12ESP705 FUNGICIDE can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable for development of bentgrass dead spot.

PRODUCT	RATE FL OZ/OZ* PRODUCT/1,000 SQ FT	DISEASE	APPLICATION INTERVAL
12ESP705 FUNGICIDE + 26GT™ or Interface StressGard or Tartan StressGard or Mirage StressGard or Daconil Ultrex® or Daconil Action® or Fore® Rainshield™	3.0 to 6.0* + 3.0 to 5.0 or 1.0 to 2.0 or 1.0 to 2.0 or 3.2* or 3.6 or 4.0 to 6.0	Summer Decline (<i>Pythium</i> and <i>Rhizoctonia</i> spp.) and/or Anthracnose (<i>Colletotrichum</i> <i>graminicola</i>)	7-14 days
12ESP705 FUNGICIDE + Interface Stressgard or Fore® Rainshield™ or Daconil Ultrex®	3.0 to 6.0 + 3.0 to 5.0 or 6.0 or 3.2*	Leaf spots Bermudagrass Decline	7-14 days

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store in original container and keep tightly closed when not in use. Store in a cool dry place. Avoid cross-contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticides wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

CONTAINER HANDLING

Rigid Non-refillable Containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable container. Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g., – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration

Top Discharge IBC, Drums, Kegs (e.g.— Snyder 120 Next Gen, Bonar B120, Drums, Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration

Non-Seed Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Non-Seed Treatment Products in Non-Refillable Foil outer pouches of Water soluble Packets (WSP)

Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken.

Rigid Non-Refillable containers with capacities smaller or equal to 5 gallons

PLASTIC CONTAINERS:

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.

SOLID Dilutable formulations:

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

Non-Seed Treatment Products in Non-Rigid, Non-refillable Containers = BAGS

Non-refillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."

Balan, Aswathy

From: Howard, Marcel
Sent: Tuesday, March 03, 2015 4:04 PM
To: Balan, Aswathy
Subject: RE: 12ESP705 (Symbol 432-RLUR) Revised Label

Hello Aswathy,

I checked my email correspondence and I did not provide any label comments for the proposed end-use product. The newly revised label was submitted based upon my conversation with Terri Moore (Bayer)... lower rates, extending application interval, etc. The most current, proposed labeling contains those additional changes, but I didn't evaluate the other portions of the label.



From: Howard, Marcel
Sent: Friday, February 27, 2015 3:47 PM
To: Balan, Aswathy
Subject: FW: 12ESP705 (Symbol 432-RLUR) Revised Label

Hello Aswathy,

Here are the revised labels for Fosetyl. Thanks for the reminder... I'll transfer the jacket on Monday.



From: Terrie Moore [<mailto:terrie.moore@bayer.com>]
Sent: Thursday, February 05, 2015 2:22 PM

To: Howard, Marcel
Subject: 12ESP705 (Symbol 432-RLUR) Revised Label

Hi Marcel,

I am sorry that I am late in getting the revised label to you. Our label specialist was out for a few days. I have attached the label shaded and unshaded with the changes and then the original label that I submitted for the 12ESP705. Please let me know if you have any questions or would like to discuss. Thank you again for considering these changes!

Have a great day!

Best Regards / Freundliche Grüße / Vriendelijke Groeten / Cordialement,

Terrie Moore, Ph.D
Regulatory Affairs Manager



Bayer CropScience

Science For A Better Life

Bayer CropScience LP
Environmental Science
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Howard, Marcel

From: Terrie Moore <terrie.moore@bayer.com>
Sent: Tuesday, January 20, 2015 12:12 PM
To: Howard, Marcel
Subject: 12ESP705 (Symbol 432-RLUR) Questions

Hi Marcel,

I was wondering if you had some time this week to discuss a few things concerning the product 12ESP705? I would like to discuss with you a name change and some possible label changes. The changes I would like to discuss is

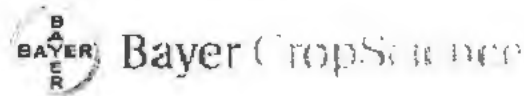
- Lowering the rates
- Extending the application interval
- Removing some redundant sentences
- Adding a footnote to correct the application window for stress management
- Changing the name of the product and adding ABNs

Do you have some time later this week to discuss the possibility of these changes? I am available on Wed. after 1pm, Thurs. 2-3pm, and Friday after 2pm. Please let me know when would be a good time for you to discuss. If this week does not work for you then I could try to schedule something with you next week. Thank you for the consideration!

Have a great day!

Best Regards / Freundliche Grüße / Vriendelijke Groeten / Cordialement,

Terrie Moore, Ph.D
Regulatory Affairs Manager



Science For A Better Life

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FEE

DP BARCODE No.: 423190; REG/FILE SYMBOL No.: 432-RLUR; PRODUCT NAME: 12ESP705
Fungicide; DECISION No.: 493775; PC Code(s): 123301; ACTION CODE: R310; FOOD Use: No

DATE OUT: January 26, 2015

SUBJECT: End Use Product Chemistry Review
Product Name: 12ESP705 Fungicide

FROM: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

Shyam Mathur
01-28-15
J.R.

TO: Marcel Howard / Shaja Joyner, RM 20
Fungicide Branch / RD (7505P)

Company Name: Bayer Environmental Sciences
Formulation Type: Fungicide

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "12ESP705 Fungicide". The registrant has submitted a CSF for basic formulation dated May 16, 2014 and the supporting product chemistry data with MRID No(s). 493294-01. CITAB has been asked to determine the acceptability of the proposed CSF(s) and the supporting product chemistry data

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fosetyl-Al (60.0%)

2. Has the registrant claimed substantial similarity to a registered product?

☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.

EPA Reg. No:

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No

4. All inert ingredients have been screened by IIAB (and found to be approved for the proposed labeled uses.

DP BARCODE No.: 423190; REG/FILE SYMBOL No.: 432-RLUR; PRODUCT NAME: 12ESP705
Fungicide; DECISION No.: 493775; PC Code(s): 123301; ACTION CODE: R310; FOOD Use: No

5. Confidential Statement of Formula(s):

☒ Basic – Dated: May 16, 2014; Re-submitted – Dated:

☐ Alternate CSF – Dated:; Re-submitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (Inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: 423190; REG/FILE SYMBOL No.: 432-RLUR; PRODUCT NAME: 12ESP705
 Fungicide; DECISION No.: 493775; PC Code(s): 123301; ACTION CODE: R310; FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	493294-01
830.1600	Description of materials used to produce the product		X		A	493294-01
830.1650	Description of formulation process		X		N	493294-01
830.1670	Discussion on the formation of impurities		X		A	493294-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	493294-01. Non-standard certified limits have been proposed for few inert ingredients with appropriate justifications
		Proposed Limits	X		A	
		Justification for wider limits	X		A	
830.1800	Enforcement analytical method		X		NA	493294-01 (Titration method)

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: 423190; REG/FILE SYMBOL No.: 432-RLUR; PRODUCT NAME 12ESP705
 Fungicide; DECISION No.: 493775; PC Code(s): 123301; ACTION CODE: R310; FOOD Use: No

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid	A	493294-01
830.6315	Flammability	The product contains no flammable components.	NA	493294-01
830.6316	Explodability	The product contains no explosive components.	NA	493294-01
830.7000	pH	3.2	N	493294-01
830.7300	Density (units)	33.106 lbs/ft ³	N	493294-01
830.7100	Viscosity	The product is a solid.	NA	493294-01
830.6317	Storage stability (*Accelerated or 1 year study)	Under Progress	I	493294-01
830.6320	Corrosion characteristics (* Accelerated or 1 year)	Under progress	I	493294-01
830.6314	Oxidation/Reduction	Does not contain any ingredient which is considered to be an oxidizer or reducing agent	A	493294-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

*Note: 830.6317 & 830.6320: The Agency will not accept the accelerated studies (54°C for 2 weeks) for these two guidelines, if the product fails this test then long range studies are required.

DP BARCODE No.: 423190; **REG/FILE SYMBOL No.:** 432-RLUR; **PRODUCT NAME:** 12ESP705
Fungicide; **DECISION No.:** 493775; **PC Code(s):** 123301; **ACTION CODE:** R310; **FOOD Use:** No

CONCLUSIONS:

The CITAB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of the materials used to produce the product), 1830.650 (description of the formulation process), 830.1670 (discussion of the formation of impurities) and 830.1800 (enforcement analytical method) are acceptable.
2. The proposed CSF for basic formulation (dated May 16, 2015) is acceptable. The registrant proposed wider certified few of the inert ingredients and has provided adequate justification. The certified limits of the other inert ingredients are within the compliance with 40CFR§158.350.
3. The product chemistry data submitted for group B data submitted are acceptable. The registrant has stated that the studies corresponding to the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) (guideline 830.6320) are in progress and the results will be submitted on completion.
4. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the RM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

07/JAN/2015

MEMORANDUM: Acute Toxicity Data Evaluation Record (DER) for 12ESP705 Fungicide

Subject: Name of Pesticide Product: 12ESP705 Fungicide
EPA File Symbol: 432-RLUR
DP Barcode: D423189
Decision No.: 493775
Action Code: R310
PC Codes: 123301

From: Tracy Keigwin, Biologist *TK*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P) *SCR*

To: Shaja Joyner
Fungicide and Herbicide Branch
Registration Division (7505P)

Applicant: Bayer Environmental Science, A Division of Bayer CropScience
2 T.W. Alexander Dr
Research Triangle Park, NC 27709

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fosetyl-Al	60.00
<u>Other Ingredient(s):</u>	<u>40.00</u>
Total: 100.0%	

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity studies submitted in support of EPA File Symbol 432-RLUR, 12ESP705 Fungicide.

BACKGROUND: Bayer Environmental Science has submitted an application for the registration of EPA File Symbol 432-RLUR, 12ESP705 Fungicide. In support of this product, the registrant has submitted the following acute toxicity studies: MRIDs 49329402 (870.1100), 49329403 (870.1200), 49329404 (870.1300), 49329405 (870.2400), 49329406 (870.2500), and 49329407 (870.2600). The product label states that 12ESP705 Fungicide is "...a plant health promoting systemic fungicide that alleviates stress from both abiotic and biotic sources".

GLP: All studies were conducted in accordance with GLP.

DEFICIENCIES/DEVIATIONS: None

COMMENTS AND RECOMMENDATIONS:

1) All 6 studies are acceptable. The acute toxicity profile of EPA File Symbol 432-RLUR, 12ESP705 Fungicide is as follows:

acute oral toxicity	III	Acceptable	MRID 49329402
acute dermal toxicity	IV	Acceptable	MRID 49329403
acute inhalation toxicity	IV	Acceptable	MRID 49329404
primary eye irritation	III	Acceptable	MRID 49329405
Primary skin irritation	IV	Acceptable	MRID 49329406
dermal sensitization	NO	Acceptable	MRID 49329407

2) CITAB notes that the PPE listed on the product label is more protective than the PPE based solely on the acute toxicity categories. If the labeled PPE is due to reasons other than the acute toxicity categories please let CITAB know so this review can be revised.

2) The Basic CSF (dated May 16, 2014) must be accepted by the product chemistry team before this action is finalized.

The following are the precautionary and first aid statements for this product (next page):

PRODUCT ID #: 432-RLUR (432-1541)

PRODUCT NAME: 12ESP705 Fungicide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear protective eyewear*, long-sleeved shirt and long pants, socks and shoes. Remove and wash contaminated clothing before reuse.

*Protective eyewear may be worn if appropriate.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Reviewer: Tracy Keigwin
Risk Manager (EPA): Shaja Joyner

Date: January 7, 2015

The following table is the Acute Toxicity Data Evaluation Record (DER) for the six studies submitted for the proposed product, EPA File Symbol 432-RLUR:

1. DP BARCODE: 423189				
2. PC CODES: 123301				
3. CURRENT DATE: January 7, 2015				
4. TEST MATERIAL: 12ESP705 (Lot # 2014-004361; PSL Reference Number 1400404-ID; Purity: Fosetyl Aluminum 60.70%; Green water dispersible granules; pH: 3.15 in 10% solution).				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat PSL (Dayton, NJ) Study #38595/July 24, 2014 OCSPP 870.1100; OECD 425	49329402	LD ₅₀ Females=5000 mg/kg bw. The test material was administered as a 50% w/w mixture in distilled water. At <u>175 mg/kg</u> (1 rat), <u>550 mg/kg</u> (1 rat) and <u>1750 mg/kg</u> (3 rats) all survived. No clinical abnormalities observed at the 175 mg/kg concentration. Test animals at the 550 mg/kg and 1750 mg/kg dose levels exhibited green feces, recovering by study day 3. No other clinical signs observed. No gross abnormalities observed at any of the above dose levels at necropsy. At <u>5000 mg/kg</u> (5 rats) 4 animals died within 1 day of dosing. Prior to death these rats exhibited hypoactivity, irregular respiration, hunched posture, ocular discharge, reduced fecal volume and/or soft feces. The surviving animal exhibited hypoactivity, hunched posture, irregular respiration and green feces, recovering by study day 4. At necropsy decedents exhibited a distension of the stomach with green fluid and/or a discoloration of the lungs. No gross abnormalities observed in the surviving animal at necropsy.	III	A

Acute dermal toxicity / rat PSL (Dayton, NJ) Study #38596/July 24, 2014 OCSP 870.1200; OECD 402	49329403	LD ₅₀ > 5000 mg/kg (both sexes-5 males and 5 females tested). No deaths. Erythema and/or desquamation was observed in 3/5 males and 5/5 females, resolving in all by study day 6. Two males and one female lost weight by the day 7 observation, however all surpassed their initial body weight by study termination. No other clinical abnormalities observed. No gross abnormalities observed at necropsy.	IV	A
Acute inhalation toxicity / rat PSL (Dayton, NJ) Study #38597/July 24, 2014 OCSP 870.1200; OECD 403	49329404	LC ₅₀ > 5.22 mg/L (Nose-only, gravimetrically determined; both sexes and combined). Mean MMAD and GSD: 3.53 µm and 2.59, respectively. One male (1/5) died within 30 minutes of exposure. Prior to death this rat exhibited hypoactivity, irregular respiration and a prone posture. Surviving animals exhibited irregular respiration, hypoactivity, ano-genital staining, gasping and/or nasal discharge, recovering by study day 9. All animals lost weight during the study, however all except for one male exceeded their initial weight by study termination (day 14). At necropsy the decedent exhibited a discoloration of the lungs and a distension of the stomach. No gross abnormalities observed in surviving animals at necropsy.	IV	A
Primary eye irritation / rabbit PSL (Dayton, NJ) Study #38598/July 24, 2014 OCSP 870.2400; OECD 405	49329405	No iritis observed. Corneal opacity was observed in 3/3 at the 24 hour observation, continuing in 2/3 through the 48 hour observation. Grade 2-3 redness and/or chemosis was observed in 3/3 from the 1 hour	III	A

		observation through the 72 hour observation, continuing in 1/3 through the day 4 observation. Green staining on the fur around the eye noted in all rabbits (3/3) at the 1 hour observation through the 48 hour observation, continuing in 2/3 through the day 7 observation. All scores zero by the day 7 observation 15.7.		
Primary dermal irritation / rabbit PSL (Dayton, NJ) Study #38599/July 24, 2014 OCSP 870.2500; OECD 404	49329406	PDI = 0.0 (non-irritating). No erythema or edema observed. No clinical signs observed. PDII = 0.	IV	A
Dermal sensitization (LLNA)/ Mouse PSL (Dayton, NJ) Study #38600/July 24, 2014 OCSP 870.2600; OECD 429	49329407	Product is <u>not</u> a dermal sensitizer. 5 groups tested – a vehicle control group (1% Pluronic L92 Surfactant w/w in distilled water), a positive control group (25% HCA in 1% Pluronic L92 Surfactant w/w in distilled water), and a test substance group (10%, 25% and 50% test substance in 1% Pluronic L92 surfactant w/w in distilled water). Animals treated with 10%, 25%, and 50% concentrations of the test substance had SI values of 1.76, 1.72 and 2.93, respectively (<3 not considered a positive response). SI value for positive control group (25% HCA) was 3.85 (acceptable).	No	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 8-1-14

Experts In-Processing Signature: B.B.

Date 8-5-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>432-RLUR</u>		EPA Receipt Date: <u>8-1-14</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-17) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Submitted studies PASSED PRN 11-3 review

* Inerts approved for non-food use

* Jacket PASSED

Lu

MRIN 493294

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis	✓					
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explosibility	✓					
830.6317	Storage stability	✓					
830.6319	Miscibility	✓					
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage	✓					
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	✓			
870.1200	Acute Dermal (LD50)	✓			
870.1300	Acute Inhalation (LC50)	✓			
870.2400	Acute Eye Irritation	✓			
870.2500	Acute Dermal Irritation	✓			
870.2600	Dermal Sensitization	✓			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					N/A
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					N/A
810.3300	Treatments to Control Pests of Humans and Pets					N/A
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					N/A
810.3500	Premises Treatments					N/A
810.3600	Structural Treatments					N/A
810.3800	Methods for Efficacy Testing of Termite Baits					N/A



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 01, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BAYER ENVIRONMENTAL SCIENCE
2 T. W. ALEXANDER DRIVE
PO.BOX : 12014
RESEARCH TRIANGLE PARK, NC 27709

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 01-AUG-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 4, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-493775
EPA File Symbol or Registration Number: 432-RLUR
Product Name: 12ESP705 Fungicide
EPA Receipt Date: 01-Aug-2014
EPA Company Number: 432
Company Name: BAYER ENVIRONMENTAL SCIENCE

TERRIE MOORE
BAYER ENVIRONMENTAL SCIENCE
A DIVISION OF BAYER CROPSCIENCE LP
2 T. W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY::PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY;CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Peresa Brown

Front End Processing Staff

Information Technology & Resources Management Division

{955819Q~

for Division

○ AD

- BPPD

RD

Risk Mgr. 20

S-

432-RLUR

8/1/2014

Parent/Child Decisions:

12310

2310

☐ Uncleared Inert in Product

Date: 2/19/14

PM - note the REI discussion

e-Submission

BNY MELLON, N.A.
PITTSBURGH 15262



Bayer
Pittsburgh, PA 15262

Contact for Questions
1-866-283-6752

CHECK NO. 3200189110

60-160
433

PAY:

***FIVE THOUSAND FORTY-EIGHT AND
00/100 DOLLARS***

*
* VOID 180 DAYS AFTER DATE OF CHECK
*
* DATE: 05-27-14 \$*****5,048.00
*

TO
THE
ORDER
OF

ENVIRONMENTAL PROTECTION AGENCY
USEPA WASHINGTON FINANCE CENTER
PESTICIDE REGISTRATION SERVICE
PO BOX 979074
ST. LOUIS MO 63197-9000

Authorized Signatures

Grace J. Spindel
Daniel J. Allen



⑈ 3 200 189 110 ⑈

Commercial/financial information may be entitled to confidential treatment



Bayer
Pittsburgh, PA 15262

Contact for Questions
1-866-283-6752

PBC/528 BEPRW

VENDOR NO.	VENDOR NAME	DATE	CHECK NO.	CHECK AMOUNT	
6768799	Environmental Protection Agency	05-27-14	3200189110	5,048.00	
REFERENCE NO.	DATE	DOCUMENT NO	GROSS AMOUNT	DISCOUNT	NET AMOUNT
IP25051410343257 12ESP705 Submission Fees	05-25-14	2400502227	5,048.00	0.00	5,048.00



M-486882-01-1

e-Submission

S: 955819 Mileston . email: terrie.moore@bayer.com

Regulatory Type: Product Registration - Section 3
Application Type: New Registration

Fee For Service: ☒ Yes ☐ No
Billable: ☒ Yes ☐ No

Print Letter
Enter More Information
Tracking

Company: 432 BAYER ENVIRONMENTAL SCIENCE

V

Risk Manager: Registration Division, Risk Management Team 20

Product #: 432-RLUR Product Name: 12ESP705 Fungicide

Me Too Section3: Me Too Product Name:

Application Date: 25-Jul-2014 ☒ OPP Rec'd Date: 01-Aug-2014 ☒
Front End Date: 01-Aug-2014 ☒ Risk Manager Send Date: ☒
FFS Due Date: Negotiated Due Date:
OPP Target Date:

Receipt Content
Study
CSF
...

New Ingredient: View/Edit
Receipt Description:
Associated with e-Submission pkg 6261 Application for new end-use product for use on turf



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-XXXX RLUR	2. EPA Product Manager Shaja Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 12ESP705	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience, Environmental Science division 2 T.W. Alexander Drive, RTP, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of the Registration of a new product for Turf use containing Foseydt-AI

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4.5 lbs, 9 lbs		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Terrie Moore	Title Regulatory Affairs Manager	Telephone No. (Include Area Code) 919-549-5678
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) M-491861-01-1
2. Signature 	3. Title Regulatory Affairs Manager	
4. Typed Name Terrie Moore	5. Date 7/25/14	

e-Submission

Bayer CropScience



July 25, 2014

Ms. Shaja Joyner
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: **12ESP705 (432-XXXX):** Submission of new end-use product for use on turf.

Dear Ms. Joyner,

Bayer Environmental Science would like to submit a new end-use product 12ESP705 (432-XXXX) for use on turf.

12ESP705 is a new end-use product containing fosetyl-Al. The [REDACTED] is registered under the EPA number [REDACTED]. We would like to submit 12ESP705 for a new end-use product with a registered source of active ingredient (R310).

The benefits of 12ESP705 include an improved formulation that provides protection from Pythium complexes and key stress diseases including summer and winter decline. 12ESP705 will also promote healthier roots, increases plant drought tolerance, and improves plant water utilization leading to enhanced stress protection. 12ESP705 could also help with managing resistance issues since it has a non-DMI active ingredient.

A 12-hr REI has been used on fosetyl-Al labels (Alliette® and Signature™) dating back to 1998. The REI of 48-hours, consistent with the WPS, is based on the technical material being a Toxicity Category I for primary eye irritation. However, the formulation 12ESP705 is a Toxicity Category III overall and for eye irritation. Moreover, this product will be used on turf for sod farms where the potential for eye contact is low. A 48-hour REI would substantially decrease the product's usefulness to growers. Bayer Environmental Science would like to request that the 12-hour REI be maintained (justification attached).

Enclosed with this submission are the following documents:

- Form 8570-1 Application Form
- Form 8570-4 for 1 Basic CSF
- Form 8570-27
- Form 8570-34
- Copy of PRIA check for \$5048
- Data Matrix for 12ESP705
- 12ESP705 Label
- REI justification and CA Incidence Report (attached)

e-Submission



M-490032-01-1

Product ingredient source information may be entitled to confidential treatment

If you have any questions, please contact me at (919) 549-5678 or email me at terrie.moore@bayer.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Terrie Moore', with a long horizontal flourish extending to the right.

Terrie Moore
Regulatory Affairs Manager

Justification for 12 hr REI

Based on our sales records, approximately 85% of our fosetyl-Al containing products are used in California. California's illness incident reports and pesticide use data from 2006-2011 contains 33 cases with 6 incidents (attached). Only one of these incidents (2006), classified as possible, involved fosetyl-Al as the only active ingredient and involved eye irritation. This incident occurred when a worker entered a lettuce field to collect irrigation pipe unaware that the field had been treated 5 hours earlier. In 2010, an incident in Monterey County involved school children being exposed to spray from a helicopter application. Eye irritation was noted. Although this is not a reentry incident, it does indicate that the California PISP system captures potential incidents including eye irritation. All other incidents involved multiple active ingredients; involved drift or other circumstances unrelated to reentry to a field treated with fosetyl-Al, and did not involve eye irritation as a symptom. There are no reported incidents for turf on sod farms. Based on the favorable safety profile of I2ESP705 and demonstrated safety over numerous years of product use, Bayer CropScience requests that a 12-hour REI be maintained.

Bayer CropScience

**TRANSMITTAL DOCUMENT**

RLUR
432-XXXX 12ESP705 Fungicide

CP-REG-OPPTS-USA-D-011018

Transmittal Date

July 31, 2014

f.v. 72

Company Official:

Company Name:

Bayer Environmental Science

Company Contact:

Moore, Terrie

Company Telephone:

+1 919-549-5678

Bayer Environmental Science
2 T.W. Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

e-Submission

M-492711-01-1

BIB. GEOGRAPHY OF SUBMITTED DATA

Study No.	Study	Guideline No.	EPA MRID No.
RPT Study Reports			
Series 830 Product Properties Test Guidelines			
830 Group A Product Identity, Composition, & Analysis Test Guidelines			
1	Cheek, R.: Product chemistry of 121-SP705, Bayer CropScience LP, RTP, NC, USA, Report No. 13R-2734, Document No. M-492386-01-1, July 24, 2014, Pages: 214	830 1550 830 1600 830 1620 830 1650 830 1670 830 1700 830 1750 830 1800 830 1900 830 6302 830 6303 830 6304 830 6313 830 6314 830 6315 830 6316 830 6317 830 6319 830 6320 830 6321 830 7000 830 7050 830 7100 830 7200 830 7220 830 7300 830 7370 830 7550 830 7560 830 7570 830 7840 830 7860 830 7950	49329401
Series 870 Health Effects Test Guidelines			
870 Group A Acute Toxicity Test Guidelines			
2	Merrill, D.: 121-SP705, Acute oral toxicity - Up-and-down procedure in rats, Product Safety Labs, Dayton, NJ, USA, Report No. 38595, Document No. M-492369-01-1, July 24, 2014, Pages: 19	870 1100	49329402
3	Merrill, D.: 121-SP705, Acute dermal toxicity in rats, Product Safety Labs, Dayton, NJ, USA, Report No. 38596, Document No. M-492370-01-1, July 24, 2014, Pages: 16	870 1200	49329403
4	Merrill, D.: 121-SP705, Acute inhalation toxicity in rats, Product Safety Labs, Dayton, NJ, USA, Report No. 38597, Document No. M-492383-01-1, July 24, 2014, Pages: 26	870 1300	49329404
5	Merrill, D.: 121-SP705, Primary eye irritation in rabbits, Product Safety Labs, Dayton, NJ, USA, Report No. 38598, Document No. M-492372-01-1, July 24, 2014, Pages: 20	870 2400	49329405
6	Merrill, D.: 121-SP705, Primary skin irritation in rabbits, Product Safety Labs, Dayton, NJ, USA, Report No. 38599, Document No. M-492381-01-1, July 24, 2014, Pages: 17	870 2500	49329406
7	Merrill, D.: 121-SP705, Local lymph node assay (LLNA) in mice, Product Safety Labs, Dayton, NJ, USA, Report No. 38600, Document No. M-492380-01-1, July 24, 2014, Pages: 27	870 2600	49329407

Start Year: 2009
End Year: 2011
Publisher: Emerald
Agribusiness & Finance Series

e-Submission

[illegible]

Year Class	Student's Name	Gender	Birth Date	Birth Place	Religion	Marital Status	Education	Occupation	Address	Remarks
2020	MONTEREY	M	12/13	Monterey, California	Protestant	Single	High School	Student	1234 Main St, Monterey, CA 93940	Student is active in school sports and community service.
2021	MONTEREY	M	12/14	Monterey, California	Protestant	Single	High School	Student	1234 Main St, Monterey, CA 93940	Student is active in school sports and community service.
2022	MONTEREY	M	12/15	Monterey, California	Protestant	Single	High School	Student	1234 Main St, Monterey, CA 93940	Student is active in school sports and community service.
2023	MONTEREY	M	12/16	Monterey, California	Protestant	Single	High School	Student	1234 Main St, Monterey, CA 93940	Student is active in school sports and community service.
2024	MONTEREY	M	12/17	Monterey, California	Protestant	Single	High School	Student	1234 Main St, Monterey, CA 93940	Student is active in school sports and community service.

[illegible]



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Bayer CropScience (Environmental Science division) 2 T.W Alexander Drive Research Triangle Park, NC, 27709	EPA File Symbol/Registration Number 432- XXXX RLUR
	Product Name 12ESP705
	Date of Confidential Statement of Formula (EPA Form 8570-4) 05/16/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fosetyl-Al

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fosetyl-Al	[REDACTED]	[REDACTED]
<i>*Product ingredient source information may be entitled to confidential treatment*</i>		
Signature <i>[Signature]</i>	Name and Title Terrie Moore, Regulatory Affairs	Date 07/25/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy



M-491865-01-1

e-Submittal



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Bayer Environmental Science, 2, T.W. Alexander drive, RTP, NC 27709. 919-549-2319	EPA Registration Number/File Symbol 432- 100 R LUR.
Active Ingredient(s) and/or representative test compound(s) Fosetyl-Al	Date 7/25/14
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial non food crop use	Product Name 12E SP705

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Terrie Moore

Date

7/25/14

Typed or Printed Name and Title

Terrie Moore, Regulatory Affairs Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.



M-491862-01-1

e-Submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-01634

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for Reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: July 31, 2014	EPA Reg. No./File Symbol: 432-RLUR	Page 1 of 5
Applicant's/Registrant's Name & Address: Bayer Environmental Science 2 T.W. Alexander Drive Research Triangle Park NC 27709 Durham United States of America		Product(s): 432-XXXX 12ESP705 Fungicide

Ingredient: Fosetyl AL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
RPT Study Reports					
Series 830 Series 830 Product Properties Test Guidelines					
830 Group A Product Identity, Composition, & Analysis Test Guidelines					
830.1550	Product Identity & Composition	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1600	Description Of Materials Used To Produce the Product	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1620	Description Of Production Process	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1650	Description Of Formulation Process	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1670	Discussion Of Formation Of Impurities	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1700	Preliminary Analysis	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1750	Certified Limits	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002

Signature	Name and Title: Moore, Terrie - Federal Registration Manager	Date: July 31, 2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;
2070-0107, 2070-0122, 2070-01634

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DATA MATRIX

Date: July 31, 2014	EPA Reg. No./File Symbol: 432-RLUR	Page 2 of 5
Applicant/s/Registrant/s Name & Address: Bayer Environmental Science 2 T.W. Alexander Drive Research Triangle Park NC 27709 Durham United States of America		Product(s): 432-XXXX 12ESP705

Ingredient: 432-XXXX 12ESP705

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800	Enforcement Analytical Method	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.1900	Submittal Of Samples	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002

830 Group B Physical/Chemical Properties Test Guidelines

830.6302	Color	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6303	Physical State	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6304	Odor	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6313	Stability To Normal & Elevated Temperatures, Metals & Metal Ions	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6314	Oxidation/Reduction: Chemical Incompatibility	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6315	Flammability	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002

Signature	Name and Title: Moore, Terrie - Federal Registration Manager	Date: July 31, 2014
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Date: July 31, 2014

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Applicant's/Registrant's Name & Address:

Bayer Environmental Science
2 T.W. Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

Product(s):

432-XXXX 12ESP705 Fungicide

Ingredient: Fosetyl AL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6317	Storage Stability	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6319	Miscibility	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6320	Corrosion Characteristics	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.6321	Dielectric Breakdown Voltage	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7000	pH	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7050	UV/Visible Absorption	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7100	Viscosity	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7200	Melting Point/Melting Range	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002

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Name and Title:
Moore, Terrie - Federal Registration
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2 T.W. Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

Product(s):
432-XXXX 12ESP705

Ingredient: 432-XXXX 12ESP705

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Point/Boiling Range	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7300	Density/Relative Density/Bulk Density	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7370	Dissociation Constants In Water	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7570	Partition Coefficient (n-octanol/water), Estimation By Liquid Chromatography	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7860	Water Solubility, Generator Column Method	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002
830.7950	Vapor Pressure	49329401	Bayer Environmental Science	OWN	M-492386-01-1 (BR 2734) Activity ID: ETFYN002

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Applicant/s/Registrant/s Name & Address: Bayer Environmental Science 2 T W. Alexander Drive Research Triangle Park NC 27709 Durham United States of America	Product(s): 432-XXXX 12ESP705 Fungicide	

Ingredient: Fosetyl AL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Series 870 Health Effects Test Guidelines					
870 Group A Acute Toxicity Test Guidelines					
870.1100	Acute Oral Toxicity (AOT)	49329402	Bayer Environmental Science	OWN	M-492369-01-1 (38595) Activity ID: TFFYN008
870.1200	Acute Dermal Toxicity	49329403	Bayer Environmental Science	OWN	M-492379-01-1 (38596) Activity ID: TFFYN008
870.1300	Acute Inhalation Toxicity	49329404	Bayer Environmental Science	OWN	M-492383-01-1 (38597) Activity ID: TFFYN008
870.2400	Acute Eye Irritation	49329405	Bayer Environmental Science	OWN	M-492372-01-1 (38598) Activity ID: TFFYN008
870.2500	Acute Dermal Irritation	49329406	Bayer Environmental Science	OWN	M-492381-01-1 (38599) Activity ID: TFFYN008
870.2600	Skin Sensitization	49329407	Bayer Environmental Science	OWN	M-492380-01-1 (38600) Activity ID: TFFYN008

Signature	Name and Title: Moore, Terrie - Federal Registration Manager	Date: July 31, 2014
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Applicant/s/Registrant/s Name & Address Bayer Environmental Science 2 T W. Alexander Drive Research Triangle Park NC 27709 Durham United States of America	Product(s): 432-XXXX 12ESP705 Fungicide	

Ingredient: Fosetyl AL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer Environmental Science	OWN	
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			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	

Signature	Name and Title: Moore, Terrie - Federal Registration Manager	Date: July 31, 2014
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Date: July 31, 2014

EPA Reg. No./File Symbol: 432-RL4R

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Applicant's/Registrant's Name & Address

Bayer Environmental Science
2 T W Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

Product(s):
432-XXXX 12ESP705

Ingredient: 432-XXXX 12ESP705

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
██████	████████████████████	██████	Bayer Environmental Science	OWN	████████████████████ ████████████████████
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Signature

Name and Title:
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Bayer Environmental Science
2 T W Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

Product(s):

432-XXXX 12ESP705 Fungicide

Ingredient Fosetyl AL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
██████	██████	██████	Bayer Environmental Science	OWN	████████████████████ ████████████████████
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Signature

Name and Title
Moore, Terne - Federal Registration
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NC 27709 Durham
United States of America

Product(s):
432-XXXX 12ESP705

Ingredient 432-XXXX 12ESP705

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
██████	████████████████████	██████	Bayer Environmental Science	OWN	████████████████████ ████████████████████
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Applicant-s/Registrant-s Name & Address:

Bayer Environmental Science
2 T W Alexander Drive
Research Triangle Park
NC 27709 Durham
United States of America

Product(s)

432-XXXX 12ESP705 Fungicide

Ingredient: Fosetyl AL

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	
			Bayer Environmental Science	OWN	

Signature

Name and Title
Moore, Terrie - Federal Registration
Manager

Date: July 31, 2014

GROUP

33

FUNGICIDE

12ESP705 FUNGICIDE

A plant health promoting systemic fungicide that alleviates stress from both abiotic and biotic sources.

ACTIVE INGREDIENT:

Aluminum tris (O-ethyl phosphonate):60.00%

OTHER INGREDIENTS:.....40.00%

TOTAL:.....100.0%

EPA Reg. No. 432-XXXX**EPA Est. No.**

KEEP OUT OF REACH OF CHILDREN
CAUTION

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-800-331-2867

Net Contents:**PRODUCED FOR****Bayer Environmental Science**

A Division of Bayer CropScience, LP
PO Box 12014 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

e-Submission

M-490034-01-1

1

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything to an unconscious person.
If in eyes	<ul style="list-style-type: none"> • Hold eyes open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. In case of medical emergency for additional information call toll free 1-800-334-7577	
NOTE TO PHYSICIAN: Treat symptomatically	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

- Harmful if swallowed
- Causes moderate eye irritation
- Avoid contact with eyes or clothing.
- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE):

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Applicators and other handlers must wear:

- Long-sleeved shirt
- Long pants
- Shoes plus socks
- Chemical-resistant (such as natural rubber) gloves (if more options are needed, follow the instructions for category A on an EPA chemical-resistance category selection chart).

Engineering Controls:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS
<p>Users should:</p> <ul style="list-style-type: none"> • Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. • Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. • Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters.

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- coveralls over long-sleeved shirt and long pants,
- socks and shoes,
- chemical-resistant gloves made of any of any waterproof material such as natural rubber \geq 14 mils

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter allow other to enter the treated area until sprays have dried

PRODUCT INFORMATION

12ESP705 FUNGICIDE is a plant health promoting systemic fungicide that alleviates stress from both abiotic and biotic sources.

For use on:

- Turf on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites.

PLANT HEALTH

12ESP705 FUNGICIDE when applied at the prescribed rates and intervals promotes healthier roots, increases plant drought tolerance, and improves plant water utilization. This leads to a reduction in the need for hand watering and a general saving of water use. The resulting improvement in function of these healthier roots leads to more efficient uptake of plant nutrients improving cell turgidity and results in a healthier and sturdier plant structure reducing the impact of traffic or mechanical damage. These effects are consistent with the properties of anti-oxidants. A property of **12ESP705 FUNGICIDE** is to act as an inducer of systemic resistance in plants resulting in production of plant metabolites responsible for maintaining plant processes.

Cool season grasses such as tall fescues, bluegrasses and bentgrasses are prone to damage during summer heat and summer decline leading to reduced root mass in the summer months. Turf treated with **12ESP705 FUNGICIDE** retains turf quality through summer stress by alleviating plant stresses, enhancing disease resistance through induced system resistance and protecting the plant from the adverse effects of solar radiation.

Warm season grasses such as bermudagrass and zoysiagrass, influenced by the effects of insufficient sunlight, are prone to losing chlorophyll and premature senescence. **12ESP705 FUNGICIDE** reduces the negative effects of low light conditions, supports earlier spring green up, turf fill in and extends turf quality.

12ESP705 FUNGICIDE when applied in a program with turf growth regulators further enhances the overall quality of the turf.

APPLICATION INFORMATION

12ESP705 FUNGICIDE must be applied as a foliar spray using ground application equipment. Apply in 1 to 5 gallons of spray solution per 1000 sq ft.

This product may cause staining. Avoid off-target sites such as sidewalks, patios, driveways, pavers, or similar materials. Do not enter treated areas until spray has dried. Rinse spray equipment thoroughly with warm water and detergent.

SPRAY MIXING AND COMPATIBILITY

12ESP705 FUNGICIDE may not be chemically compatible with foliar fertilizers or with copper-based fungicides and phytotoxicity may occur. To determine the physical compatibility of **12ESP705 FUNGICIDE** with any other product, use a small container to mix a small amount (e.g. 1 pint) of spray solution, containing all ingredients in the same order and ratio as the anticipated use. If any indication of physical incompatibility develops, do not use this mixture for spraying. Indication of incompatibility usually appears within 5 - 15 minutes after mixing. Read and follow all directions and precautions on this label and on the labels of any products for which a tank mixture is being considered.

PRODUCT USE RESTRICTIONS

- Do not graze animals on treated turf.
- Do not feed clippings from treated turf to livestock and poultry.

TURF USE DIRECTIONS

12ESP705 FUNGICIDE is a systemic fungicide, which may be used, in a seasonal program for the control of Pythium diseases, such as blight and root rot, and yellow tuft on common turfgrasses on golf courses, sod farms, sport fields, institutional, municipal, and commercial sites. Apply as a foliar spray, using 1 to 5 gallons of spray solution per 1,000 square feet, as indicated in the table below. Apply with a properly calibrated sprayer. Maintain agitation during spray operations.

PLANT HEALTH

12ESP705 FUNGICIDE has a plant health component that is used for the prevention or alleviation of stress from solar radiation and other oxidative processes on turfgrasses. Begin preventative applications prior to the occurrence of adverse weather conditions and repeat at prescribed intervals. Use higher rates prior to the onset of severe stress. **12ESP705 FUNGICIDE** does not replace the use of soil amending adjuvants for soil hydrophobicity and must be used in conjunction with best turf management practices.

STRESS MANAGEMENT	RATE OZ PRODUCT /1000 SQ FT	APPLICATION DIRECTIONS
Stress caused by periods of <ul style="list-style-type: none"> • high solar radiation • high wilt potential • winter cold • hot and humid weather • traffic wear • physical or mechanical damage • injury from the use of turf growth regulators • injury from disease 	3 – 6	Apply at 7-14 day intervals as needed. Extend application interval beyond 14 days when climatic conditions are less favorable for turf growth. Do not mow or irrigate treated area until sprays have completely dried.

APPLICATIONS FOR TURF DISEASES

DISEASE	RATE OZ PRODUCT /1000 SQ FT	INTERVAL OF APPLICATIONS (DAYS)	APPLICATION DIRECTIONS
Pythium diseases, Yellow turf	3 – 6	7-14	Begin preventive foliar spray application when conditions first favor disease and repeat at prescribed interval. Apply approved amount in 1 to 2 gallons of solution per 1000 sq ft. Use the highest rate for the longer interval. Do not mow or irrigate treated area until sprays have completely dried.
Bacterial Wilt	6	7-14	Use 2 to 4 gallons of solution /1000 sq ft. Use the more frequent interval when severe symptoms appear.

USE AS A RESISTANCE MANAGEMENT TOOL

Fosetyl-Al has no history of resistance development in plant pathogenic fungi; include **12ESP705 FUNGICIDE** as a mixture or rotation partner in programs to manage resistance for fungicides with a high risk of resistance to labeled diseases.

TANK MIXTURES

A **12ESP705 FUNGICIDE** program encourages the development of a thick, vigorous turf stand that is better able to tolerate various stresses (heat, humidity, drying winds, traffic etc) that can have a negative effect on turf health. A thick, vigorous **12ESP705 FUNGICIDE** treated turf is better able to resist disease development and suppress the development of other pests such as weeds and algae.

Summer Decline: For control of Summer Decline caused by a complex of Pythium and Rhizoctonia diseases, **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. Do not exceed label dosage rates. This product cannot be mixed with any product containing a label prohibition against such mixing.

Anthracnose: For improved control of anthracnose **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable to anthracnose.

Bentgrass Dead Spot: For control of bentgrass dead spot, **12ESP705 FUNGICIDE** can be tank-mixed with the products listed below in accordance with the most restrictive of label limitations and precautions. A preventative, multi-application program must be started prior to the appearance of the disease and the conditions favorable for development of bentgrass dead spot.

PRODUCT	RATE FL OZ/OZ* PRODUCT/1,000 SQ FT	DISEASE	APPLICATION INTERVAL
12ESP705 FUNGICIDE + 26GT™ or Interface StressGard or Tartan StressGard or Mirage StressGard or Daconil Ultrex® or Daconil Action® or Fore® Rainshield™	3.0 to 6.0* + 3.0 to 5.0 or 1.0 to 2.0 or 1.0 to 2.0 or 3.2* or 3.6 or 4.0 to 6.0	Summer Decline (Pythium and Rhizoctonia spp.) and/or Anthracnose (Colletotrichum graminicola)	7-14 days
12ESP705 FUNGICIDE + Fore® Rainshield™ or Daconil Ultrex®	3.0 to 6.0 + 6.0 or 3.2*	Leaf spots Bermudagrass Decline	7-14 days

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE

Store in original container and keep tightly closed when not in use. Store in a cool dry place. Avoid cross-contamination with other pesticides.

PESTICIDE DISPOSAL

Pesticides wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency or Hazardous Waste representative at the nearest EPA regional office for guidance in proper disposal methods.

CONTAINER HANDLING

Rigid Non-refillable Containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable container. Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration

Non-Seed Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Non-Seed Treatment Products in Non-Refillable Foil outer pouches of Water soluble Packets (WSP)

Offer foil pouch for recycling if available or dispose of empty pouch in the trash as long as WSP is unbroken.

Rigid Non-Refillable containers with capacities smaller or equal to 5 gallons

PLASTIC CONTAINERS:

Non refillable container. Do not reuse or refill this container. Tripled rinse container (or equivalent) promptly after emptying.

SOLID Dilutable formulations:

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

Non-Seed Treatment Products in Non-Rigid, Non-refillable Containers = BAGS

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities."

